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Better medical apps for healthcare practitioners  
through interdisciplinary collaboration: lessons  
from transfusion medicine.

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Thesis submitted for the degree of Doctor of Philosophy

The University of Edinburgh

2016

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# Abstract

Mobile applications (“apps”) are increasingly used in medical education and practice. However, many medical apps are of variable quality, lack supporting evidence and fall outside the remit of regulators. In this thesis, I explore how the quality and credibility of apps for healthcare practitioners could be improved. I argue that interdisciplinary collaboration throughout the app life-cycle is critical and discuss how this can be facilitated. My argument rests on prior work in eHealth and neighbouring disciplines, and on original research in transfusion medicine.

Blood transfusion can be a life-saving medical treatment. However, it also carries risks. Failures to provide irradiated and cytomegalovirus-negative blood components according to guidelines are frequently reported in the UK. Such incidents put patients at risk of serious complications. Haemovigilance data indicates that enhancing practitioner knowledge may reduce mistakes. Thus, I worked with medical experts to develop and evaluate the *Special Blood Components (SBC)* mobile learning app. To facilitate this work, I created two tools: the *Web App Editor (WAE)* and the *Web App Trial (WAT)*. The former is a collaborative editor for building apps in a web browser and the latter is a system for conducting online randomised controlled app trials.

The results are reported in five studies. Studies 1 and 2, based on interviews with seven practitioners, revealed shortcomings in an existing transfusion app and the SBC prototype. Study 3 demonstrated how students using the WAE were able to collaborate on apps, including an app in stroke medicine. Study 4, an evaluation of the revised SBC app with 54 medical students, established the ease of use as acceptable. In study 5, a WAT pilot study with 61 practitioners, the SBC app doubled scores on a knowledge test and was rated more favourably than existing hospital guidelines.

In conclusion, creating high quality medical apps that are supported by evidence is a considerable undertaking and depends on a mix of knowledges and skills. It requires that healthcare practitioners, software developers and others work together effectively. Hence, the WAE and WAT are key research outcomes. They enabled participants to contribute improvements and assess the usability and efficacy of the SBC app. The results suggest that the SBC app is easy to use and can improve practitioner knowledge. Further work remains to pilot and evaluate the SBC app in a hospital setting.



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# Lay summary

Doctors, nurses and other healthcare staff increasingly use mobile devices, such as “smartphones” and “tablets”, in their work. But many medical mobile software applications (“apps” for short) are of poor quality and largely unproven. In this thesis, I investigate why this is and how medical apps for healthcare staff could be improved. To do this, I identified lessons from previous research and from a project where I worked with healthcare professionals to create a new app in blood transfusion.

Blood transfusions in the UK are very safe, but gaps in medical staff knowledge of which patients should be given specially prepared blood<sup>1</sup> lead to mistakes that can make patients very sick. To help improve staff knowledge of this topic, I created the *Special Blood Components (SBC)* mobile learning app. The SBC app was built according to comments from over one hundred doctors, nurses, medical students and others.

I also created two tools to make it easier to build and test apps with others. The first tool, the *Web App Editor (WAE)*, is a collaborative editor where several authors can work together. I used the WAE to create the SBC app and others have also used the editor to build other apps, including one for patients with stroke. The second tool, the *Web App Trial (WAT)*, is a system for testing apps with users. Using the WAT, I assessed if the SBC app improved knowledge in staff from three Scottish hospitals. I found that knowledge levels were low and improved when the SBC app was used. Staff also rated the SBC app higher than existing hospital guidelines.

In summary, improving medical apps for healthcare staff requires that people with a mix of skills and knowledges work together over a long time. Therefore, the WAE and WAT tools are important research outcomes. They made it easier to collaborate and update the SBC app according to staff comments. The tools also helped collect evidence suggesting that the SBC app is easy to use and can improve staff knowledge. Additional research in hospitals is required to know with greater certainty whether the use of the SBC app can improve patient care.

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<sup>1</sup>These special kinds of blood components are known as irradiated and cytomegalovirus-negative blood (see the main text for an in-depth explanation).

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# Declaration

I declare that this thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text, and that this work has not been submitted for any other degree or professional qualification except as specified.

.....

Karl Monsen, 2016

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## Peer-reviewed outputs

- Monsen, K. and McClelland, D. B. L. (2014). An evaluation by final year medical students of an app supporting correct use of irradiated and CMV-negative blood components. In *Abstracts of the Annual Serious Hazards of Transfusion (SHOT) Symposium, 9 July, 2014, The Lowry Theatre, Salford Quays, Manchester, UK*, volume 24. Presented at the 2014 SHOT Symposium
- Monsen, K. and McClelland, D. B. L. (2013). Is this patient in the risk zone? An app for checking the indications for irradiated and CMV negative blood. In Roberts, D., editor, *Abstracts of the XXXI Annual Scientific Meeting of the British Blood Transfusion Society, 16-18 October, 2013, Birmingham, UK*, volume 23. Supplement 2. Presented at the BBTS meeting
- Monsen, K. (2013). Transforming audiences into contributors: A development environment for enabling user-driven innovation in HTML5 apps. In *Proceedings of the Moving Targets conference, October 15-16 2013, Dundee Contemporary Arts, Scotland*.

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# Acknowledgements

I am grateful for the excellent support and guidance provided by my supervisory team: Prof. Jon Oberlander, Dr. Debbie Maxwell, Prof. Simon Biggs and Prof. Chris Speed. I am also indebted to Dr. Brian McClelland and his colleagues at the Scottish National Blood Transfusion Service (SNBTS) who have contributed extensively to the project. Many other healthcare professionals have generously supported the research, including (in alphabetical order):

- Dr. Shubha Allard, Consultant Haematologist and Chair of BCSH.
- Dr. Karen Bailie, Consultant Haematologist, SNBTS.
- Dr. Paula Bolton-Maggs, Medical Director of SHOT.
- Ms. Susan Cottrell, Nurse Specialist in Education, SNBTS.
- Mr. Amanpreet Dhesi, Patient Blood Management Team NHSBT.
- Dr. Lise Estcourt, Research Registrar, NHSBT.
- Mrs. Sandra Gray, Head of Nursing (Clinical Services), SNBTS.
- Mrs. Catherine Innes, Transfusion Practitioner, SNBTS.
- Dr. Alastair Nimmo, Consultant, Royal Infirmary of Edinburgh.
- Ms. Debbi Poles, Research Analyst, SHOT.
- Dr. Charles Wallis, ICU Consultant, Western General Hospital Edinburgh.
- Mr Douglas Watson, Clinical Effectiveness Coordinator, SNBTS.
- Ms. Alison Watt, Operations Manager, SHOT.
- Dr. Sharon Zahra, Consultant and Clinical Lead, Tissue and Cells, SNBTS.

Furthermore, Dr. Niall Anderson provided statistics advice. Staff and students at the Pennypit Community Learning Centre helped me to explore research ideas in a friendly setting. Helen Mamalaki piloted the Web App Editor while creating an app for stroke patients under the supervision of Prof. John Lee and Dr. William Whiteley. I am also grateful to the medical professionals and students who have provided feedback on the SBC app.

This thesis would not have been possible without the scholarship provided through the Design in Action knowledge exchange project. Financial support from the Edinburgh College of Art Postgraduate Research Expenses fund enabled me to attend and present at conferences both nationally and internationally. Last but not least, I want to thank my friends and family, especially Cecilia, for their support. Any omissions or mistakes are my own.



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# **Part I**

## **BACKGROUND**





# Chapter 1: Introduction

The study of the use, design and evaluation of mobile software applications (“apps”) in healthcare is an emerging area of research that is increasingly salient as more healthcare practitioners decide to use smartphones and tablets in their work and training. In this thesis, I explore this phenomenon through the collaborative development and evaluation of an app aiming to improve a challenging area of blood transfusion.

This introductory chapter begins by summarising the research aim and rationale. This is followed by an overview of the empirical setting, objectives and methodology. The main outputs, contributions to knowledge and conclusions are then outlined. The chapter concludes by signposting the remainder of the thesis.

## 1.1 Research aim and rationale

Mobile medical apps are heterogeneous software applications designed to perform or aid a large range of healthcare tasks. Running on widely adopted mobile devices, such as smartphones and tablets, apps provide healthcare practitioners with access to decision support, medical guidelines, educational materials and other resources in a familiar and portable format. As a result, many practitioners use apps in their medical education and practice on a regular basis (Mobasher et al., 2015; O'Reilly et al., 2014; Carter et al., 2014; Payne et al., 2012; Franko and Tirrell, 2012).

However, the safety and effectiveness of many medical apps is uncertain as they are of variable quality and lack supporting evidence (Boulos et al., 2014; Buijink et al., 2013; Ozdalga et al., 2012; Haffey et al., 2013b; McCartney, 2013; Derbyshire and Dancey, 2013; Eng and Lee, 2013; Bender et al., 2013; Wolf et al., 2013). Prior work suggest this is, at least in part, the result of design processes that do not sufficiently engage with users and evaluation research (Pagliari, 2007; Car et al., 2008; Masters, 2014; Visvanathan et al., 2012; Hamilton and Brady, 2012; Haffey et al., 2013b; O'Neill and Brady, 2012; Zhou et al., 2012).

**Thus, the aim of the thesis is to explore how the quality and credibility of medical apps intended for healthcare practitioners could be improved by collaborative design and evaluation processes.** I identify lessons from prior work and from a project where I collaborated with practitioners to create and evaluate apps

aiming to improve blood transfusion practice. Furthermore, as there is a shortage of established tools for developing and evaluating medical apps with others, I created a collaborative app editor and a system for conducting online randomised controlled trials of apps. Before detailing the outcomes, and the knowledge contributions that stem from them, it is necessary to elaborate the rationale of the research collaboration.

Access to safe blood transfusions is a global priority as it is a common and life-saving treatment (World Health Organization, 2008, 5). However, it is also a complex process with many possible points of failure associated with serious risks (McClelland and Philips, 1994; Contreras and de Silva, M, 1994; McClelland, 1998; Heddle et al., 2012). The purpose of the research collaboration was to improve the management of two serious complications of blood transfusion, known by the abbreviations TA-GvHD and TT-CMV (summarised in table 1.1).

Table 1.1: Characteristics and management of TA-GvHD and TT-CMV.

Transfusion-Associated Graft versus Host Disease (TA-GvHD)	Transfusion-Transmitted Cytomegalovirus infection (TT-CMV)
TA-GvHD is a rare and almost always fatal immunological condition where transfused donor lymphocytes (white blood cells) attack the recipient. TA-GvHD is prevented by providing Gamma or X-ray irradiated cellular blood components to at-risk transfusion patients. As there is no effective treatment, the correct use of irradiated blood components is critical to prevent TA-GvHD (Treleaven et al., 2010).	TT-CMV is transmission of Cytomegalovirus (CMV), a widespread herpes virus, via blood transfusion. CMV infection is usually harmless, but can lead to life-long disability or death in vulnerable patients, such as neonates. In the UK, TT-CMV was previously prevented by providing at-risk patients with blood from donors who screen negative to CMV. After universal leucodepletion (whereby cells harbouring CMV are removed) this is no longer required for most patients (SaBTO, 2012b).

Both are prevented by providing at-risk patients with correct blood components. These are manufactured using irradiated blood and/or blood from donors who are Cytomegalovirus (CMV) negative (see chapter three for additional details). However, identifying at-risk patients and ensuring that they receive these “special blood components” is challenging. In the UK, about one hundred failures are reported annually (figure 1.1), and more are likely undetected. These incidents, which put patients at risk of TA-GvHD and TT-CMV, occur in complex care environments for a range of reasons. For example, organisational and human factors causes include distractions in the workplace, miscommunication and understaffing (Bolton-Maggs et al., 2016, 22).

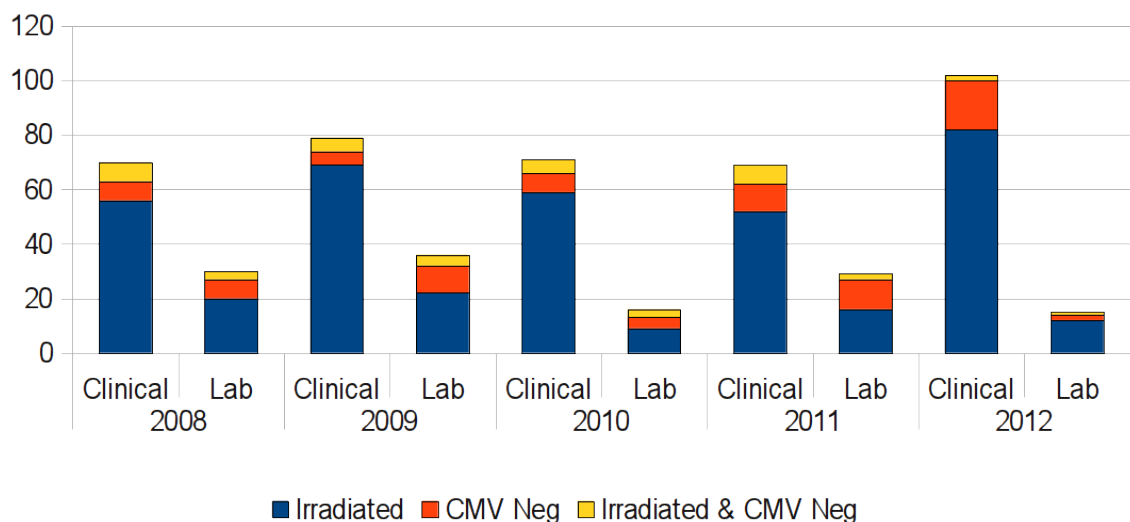


Figure 1.1: Failures to provide irradiated and/or cytomegalovirus (CMV) negative blood components reported to the Serious Hazards of Transfusion (SHOT) haemovigilance scheme between 2008 and 2012. Clinical errors include failure to communicate the need for special blood components to the lab. In lab errors, the request was made but not acted upon (Cohen et al., 2010, 27). Source: Dr. Paula Bolton-Maggs, Debbi Poles and Alison Watt. Used with permission from SHOT.

Deciding whether to provide a patient with special blood components also requires awareness and detailed knowledge of nearly two dozen clinical indications. Hence, a recurring reason for mistakes is a lack of knowledge among healthcare practitioners of the correct use of special blood components. The following example, where a patient who should have received irradiated blood was erroneously provided with non-irradiated blood, illustrates the problem (Knowles and Cohen, 2011, 26):

“The admitting doctor noted the past history of Hodgkin’s disease but was not aware of the requirements for irradiated blood.”

This case was reported to Serious Hazards of Transfusion (SHOT), a professionally-led body that monitors transfusion errors and “near-misses” in the UK. SHOT have highlighted the issue in several of their reports and have recommended that this aspect of medical education is improved (table 1.2).

Table 1.2: A selection of findings and recommendations related to the correct use of special blood components published by SHOT between 2010 and 2012.

---

“Many cases of failure to request irradiated products [—] demonstrate a lack of adequate knowledge in clinical staff”	Bolton-Maggs and Cohen (2012, 33)
“All haematology units must devise specific educational programmes for all their staff members providing the rationale and indications for specialist components and this information should be accessible at the time of making the requests”	Knowles and Cohen (2011, 28)
“The existence [...] of special transfusion requirements must be taught to junior doctors in all hospital specialities.”	Cohen et al. (2010, 55)

---

## 1.2 Justification for a mobile learning web app

Failures to provide irradiated and CMV-negative blood to at-risk patients could thus be reduced by improving practitioner knowledge. Despite SHOT's recommendations, there is a shortage of appropriate learning resources. For instance, Learn Blood Transfusion (LBT) – a continuing medical education programme used throughout the UK – does not contain detailed learning materials about this topic. Instead, the most prominent resources are the national guidelines ([Treleaven et al., 2010](#); [SaBTO, 2012b](#)), local hospital guidelines and medical handbooks (e.g. [Norfolk, 2013](#)).

However, these documents are of limited pedagogical value as they are not intended for educational use and assume prior knowledge. There is hence a need for educational resources aimed at practitioners who may be new to this topic or who want to improve their existing knowledge. This includes knowledge not just of the clinical indications, but also of topics such as the causes and mechanisms of TA-GvHD and TT-CMV, the role of immunodeficiency, immunosuppressive drugs and other relevant medical histories, the manufacture and properties of cellular blood components, genetic risk factors (shared HLA haplotypes) and common causes of mistakes.

Medical professionals are expected to know and make use of a growing amount of specialised information and medical guidelines ([Allen and Harkins, 2005](#); [Dimond et al., 2016](#)). It is therefore critical that educational interventions meet the needs of busy healthcare practitioners. Prior work suggests that the use of online learning

(e-learning) can be a flexible and effective strategy for improving knowledge of the principles of safe transfusion practice (Graham, 2015; Smith et al., 2014, 2011), while catering for diverse learning styles (Cottrell and Donaldson, 2013).

Educational materials that are designed according to the constraints of mobile devices, such as the small screen size and shorter interactions, can offer effective learning experiences (Orr, 2010, 107). Mobile devices can enable “just in time” and “bite-size” patterns of accessing information, making them, as Traxler (2007, 7) put it, “uniquely suited to support context-specific and immediate learning”. They can also be used on the ward, at the point of care and in other settings, thereby extending the reach of traditional desktop-based e-learning (Traxler, 2009, 10). Mobile devices may also help to manage information overload by functioning as cognitive aids that improve recall in a clinical situation (Low et al., 2011; Bullock et al., 2015).

With the advances in web technologies, such as widespread support for Media Queries in Cascading Style Sheets, it is possible to create mobile “web apps” that are compatible with smartphone, tablet and desktop computers (Rivoal, 2012; Orr, 2010). If developed using a framework that incorporates these technologies (Heitkötter et al., 2013), a single web app could disseminate learning materials to widely used smartphone, tablet and desktop computers, including legacy systems used in the NHS. This would open up new ways of accessing learning materials and could further the goals of continuing medical education in this area.



### 1.3 Objectives, methodology and outputs

As shown in table 1.3, the research aim was broken into seven objectives which formed the basis for two literature reviews (chapters two and three) and five empirical studies (chapters five through nine). To achieve the objectives, I adopted an action research methodology (laid out in chapter four) where I worked with domain experts, healthcare practitioners and others. Figure 1.2 summarises the main steps in the process.

I began by reviewing prior studies, existing practices and interventions, and by testing the proposed concept with potential users. I then proceeded to iteratively design and evaluate the app, while simultaneously creating collaborative tools and methods for building, sharing and evaluating work in progress with contributors. Drawing on these activities, I reflected on transferable lessons for improving the quality and credibility of medical apps for healthcare practitioners (discussed in chapter ten).

The research outputs consist of a combination of software applications and contributions to knowledge. This is a somewhat problematic distinction as software can be considered a knowledge product, is integral to research in many disciplines (Goble, 2014) and is increasingly recognised as a research contribution outside of computer science (The Software Sustainability Institute, 2015). Before discussing the knowledge contributions, I will therefore describe the three resulting software applications:

1. The Special Blood Components (SBC) app;
2. The Web App Trial (WAT) evaluation system; and
3. The Web App Editor (WAE) authoring tool.

Table 1.3: Summary of the research objectives.

- 
1. Map the key issues related to the use, design and evaluation of medical apps.
  2. Analyse the manufacture and clinical use of blood components in the UK.
  3. Review an existing blood transfusion app targeting UK healthcare practitioners.
  4. Validate and improve the proposed mobile learning app with practitioners.
  5. Create and test a collaborative authoring tool for collaborative app design.
  6. Evaluate the usability of the Special Blood Components (SBC) app.
  7. Assess the acceptability and impact of the SBC app with healthcare professionals.
- 

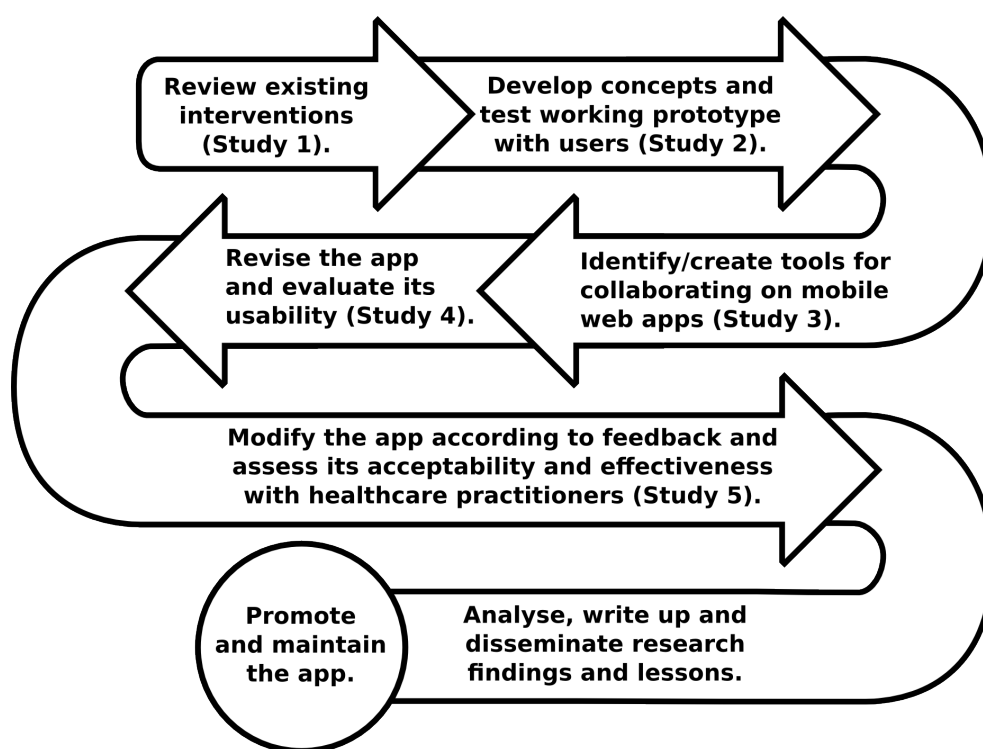


Figure 1.2: A simplified representation of the stages of the action research project. The first five phases sought to explore specific questions through a range of methods. Each phase corresponds to an empirical study, reported in chapters five through nine.

## 1.4 Special Blood Components (SBC) app

The SBC app aims to promote the correct use of irradiated and CMV-negative blood components by providing healthcare practitioners with access to learning materials and clinical indications. The usability, effectiveness and acceptability of the SBC app have been evaluated multiple times, resulting in several revisions (illustrated in figure 1.3). Designed as a responsive web app, it is compatible with smartphones, tablets and desktop computers, including legacy web browsers (Internet Explorer 6+) used in the National Health Service. Figures 1.4 and 1.5 illustrate the main screens of the app.

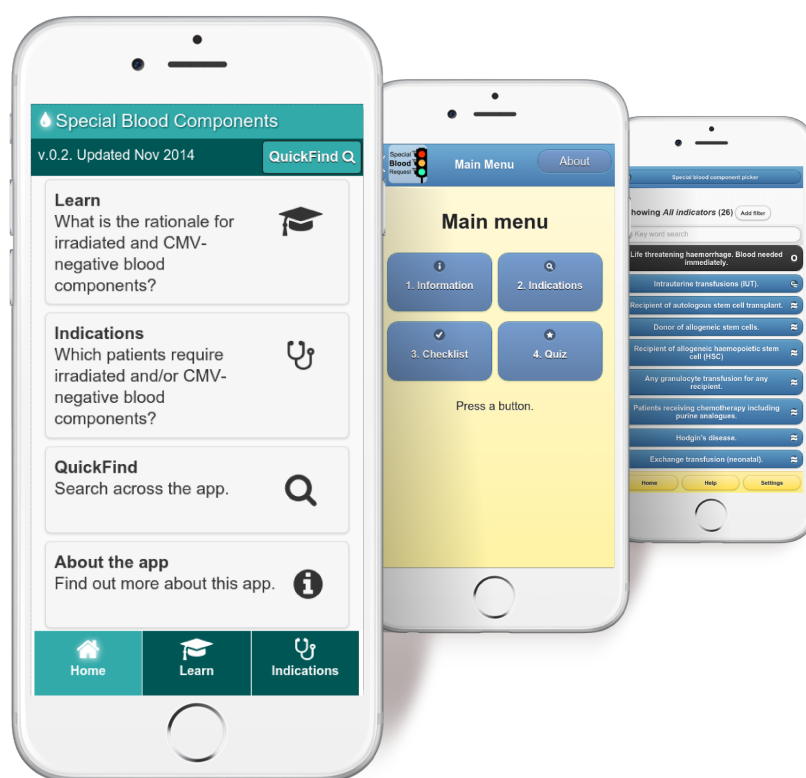


Figure 1.3: The Special Blood Components (SBC) app, showing evolution over the course of the project (from left: November 2014, September 2013 and April 2013).

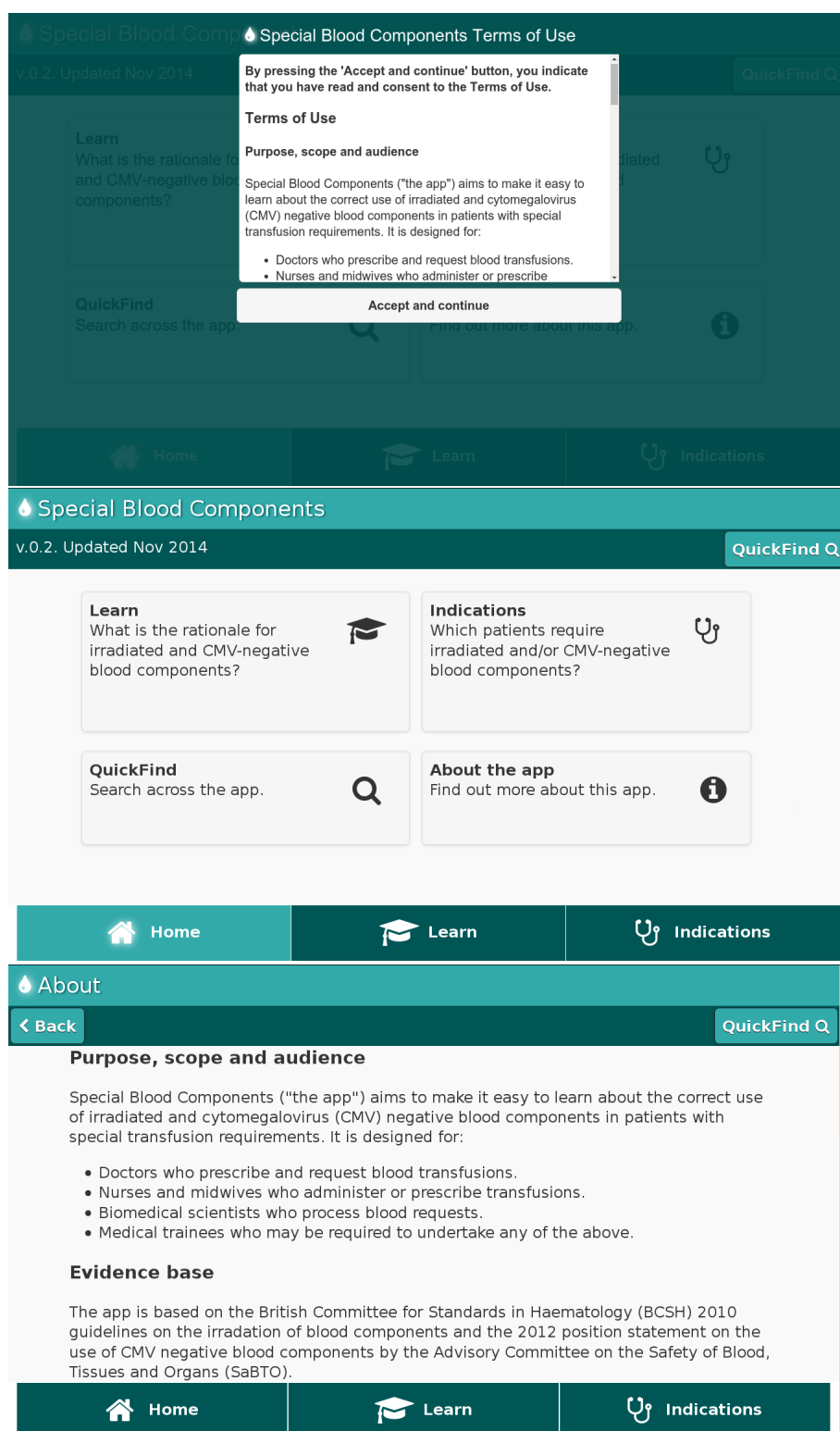


Figure 1.4: Screenshots of SBC app taken on a wide-screen display (16:9 aspect ratio) in landscape orientation (from top: "Terms of use", "Welcome" and "About" pages).

**Errors in the provision of special requirements**

Between 2008 and 2012 more than five hundred mistakes involving irradiated and CMV negative blood components were reported to the Serious Hazards of Transfusion (SHOT) UK haemovigilance scheme (see figure). These were cases when blood components failed to be provided as irradiated and/or CMV negative to patients with special requirements according to guidelines. To put this in perspective, almost three million blood components are issued annually in UK (SHOT 2009, p.11), of which approximately 10% are irradiated (SHOT 2010, p.129).

**Figure: Errors 2008-2012.**

**What are some of the causes for mistakes?**

**Indications for irradiated and CMV negative blood components**

Which patients require irradiated or CMV-negative blood components?

Press an indication to show details.

Q Search table    Filter

Indication	
+ Allogeneic haemopoietic stem cell transplant recipients.	
+ Anti-thymocyte globulin (ATG).	

**Intrauterine transfusions (IUT).**

**Irradiation is required.**  
**CMV-negative is required.**

1. "All blood for intrauterine transfusion (IUT) should be irradiated (1B)." (bcsh2010)
2. "For IUT and exchange transfusion (ET), blood should be transfused within 24 h of irradiation and, in any case, by 5 days or less from collection (1A)." (bcsh2010)
3. "CMV seronegative red cell and platelet components should be provided for intra-uterine transfusions and for neonates (ie up to 28 days post expected date of delivery)." (sabto2012)

Figure 1.5: Screenshots showing examples of the learning materials, clinical indications table and detailed recommendations offered by the SBC app.

## 1.5 Web App Trial (WAT) evaluation system

To assess the impact and acceptability of the SBC app, I created the Web App Trial (WAT) system. It is a web-based application for conducting online randomised controlled trials of web apps. Using the system, I conducted an evaluation of the SBC app with healthcare practitioners from three Scottish hospitals (reported in chapter nine). Figures 1.6-1.7 show the WAT from the perspective of a research participant.

Authenticated users can access the collected data through a web-based interface (figure 1.8). The results can be explored using graphs generated by the system or exported as comma delimited data (CSV) for statistical analysis. Like the SBC app, the WAT is compatible with smartphones, tablets and desktop computers (including legacy web browsers down to Internet Explorer 6). Key features of the WAT system are summarised in table 1.4.

Table 1.4: Key features of the Web App Trial (WAT) system.

---

✓ Support for participant information sheet and consent handling.
✓ Participant screening against inclusion criteria.
✓ Pre- and ad hoc randomisation of participants.
✓ Selective display of interventions according to user's trial arm allocation.
✓ Inline embedding of interventions alongside evaluation questions.
✓ Question order randomisation and automatic scoring.
✓ Visual indication of progression through the evaluation.
✓ Timing of user actions at key progression points.
✓ Data capture, validation, analysis and export.

---



THE UNIVERSITY of EDINBURGH

### Stopping and Preventing Errors in CMV-negative and Irradiated blood transfusions through App-based Learning (SPECIAL).

We would like to invite you to participate in the SPECIAL study. Before you decide whether to take part, click on the headings below to find out why we need your help and what we will ask you to do.

#### 1. What is the aim of the research?

Blood transfusion is a complex process and about one hundred mistakes related to the provision of irradiated and Cytomegalovirus (CMV) negative blood ("special blood components") are reported every year to Serious Hazards of Transfusion (SHOT) in the UK.

Researchers at the University of Edinburgh are collaborating with experts in transfusion to create an app with learning materials about special blood components for staff involved in key stages of the transfusion process. This pilot study will evaluate whether the app increases knowledge of the correct use of special blood components.

#### 2. What will I be asked to do?

#### 3. Why should I participate?

#### 4. How will you use my data?

#### 5. Who are you asking to participate?

#### 6. Who is conducting the research?

### Ready to begin?

Press the green button to indicate that you have read the above information and freely consent to take part in the study.



I agree to participate

Figure 1.6: Screenshot of the WAT system, showing the participant information page for the SBC app evaluation (reported in chapter eight).

**You have completed the first set of questions.**

Please take a moment to study the Special Blood Components App (adjacent) before proceeding to answer the remaining questions.

☒ I am ready to proceed

Proceed to remaining questions

Special Blood Components
v.0.2. Updated Nov 2014
QuickFind Q

**Learn**  
 What is the rationale for irradiated and CMV-negative blood components?

**Indications**  
 Which patients require irradiated and/or CMV-negative blood components?

**QuickFind**  
 Search across the app.

**About the app**  
 Find out more about this app.

Home

Learn

Indications

Figure 1.7: The Web App Trial (WAT) system as a research participant randomised to the app arm, and half-way through the evaluation, would see it.

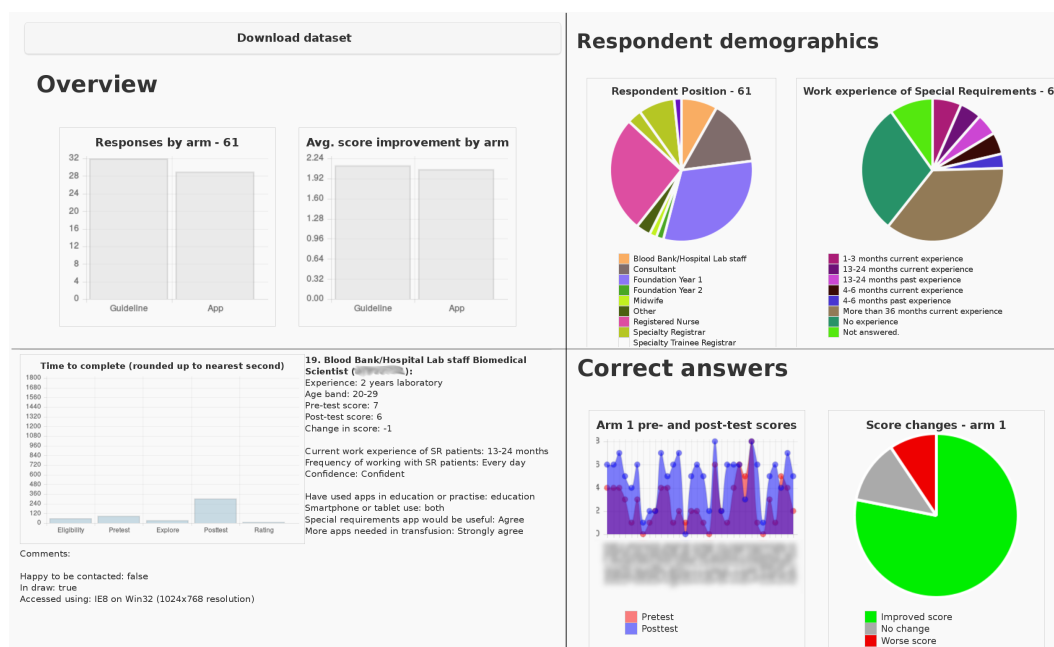


Figure 1.8: Screen captures from WAT showing the real-time analytics reported by the system (clockwise from top left corner: response rate and scores by arm; demographics; individual and aggregate scores by arm; and completion times).



## 1.6 Web App Editor (WAE) authoring tool

The third software output from the research is the Web App Editor (WAE). It is a browser-based authoring environment that enables collaborative development of web apps. I used the WAE to create the SBC app (figure 1.9) and it was also used in a Masters dissertation project to create an app that elicits symptoms of patients with transient ischaemic attack or “mini stroke” – see figure 1.10 and chapter seven for details.

I also used the editor to teach two certified introductory courses in mobile app development (examples of some of the apps created by the students are discussed in chapter seven). Thus, the WAE is both a research and development tool, as well as an outcome of the research process that evolved over the course of the project. The current version incorporates functionality from many open source software projects and the core features are summarised in table 1.5. The editor requires a Github.com account and is available at: <https://www.webappeditor.com>.

Table 1.5: Key features of the Web App Editor (WAE).

- 
- ✓ Multiple authors can collaborate on apps in real-time.
  - ✓ Quick preview of apps on mobile and desktop devices.
  - ✓ Version control through integration with GitHub.com.
  - ✓ File creation, uploading, renaming, deletion and moving.
  - ✓ Text, audio and video communication between collaborators.
  - ✓ Built-in code-highlighting, syntax linting and folding.
  - ✓ Entirely web-based without dependency on installed software.
  - ✓ Configurable user interface based on file tabs and panels.
-

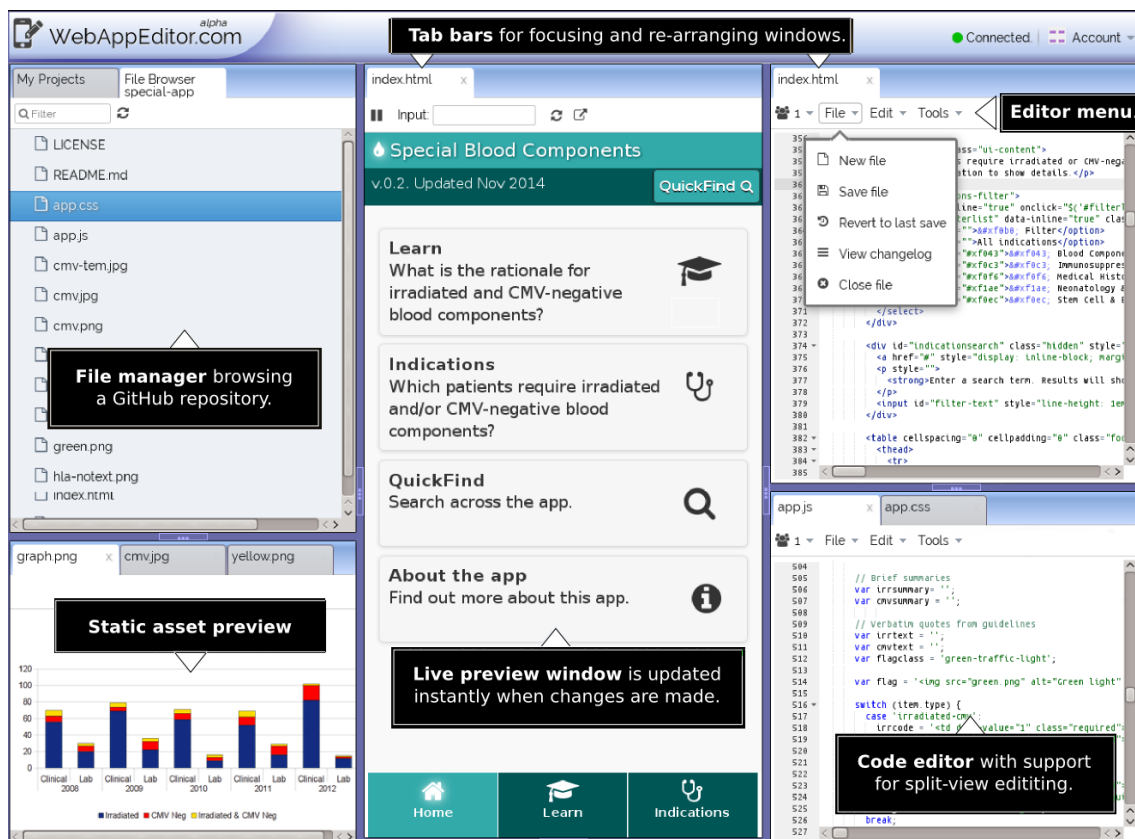


Figure 1.9: Annotated screenshot of the Web App Editor (clockwise: file manager for GitHub repository; live app preview; collaborative code editor editing an HTML file; editor with an open Javascript file; preview of a static media resource).

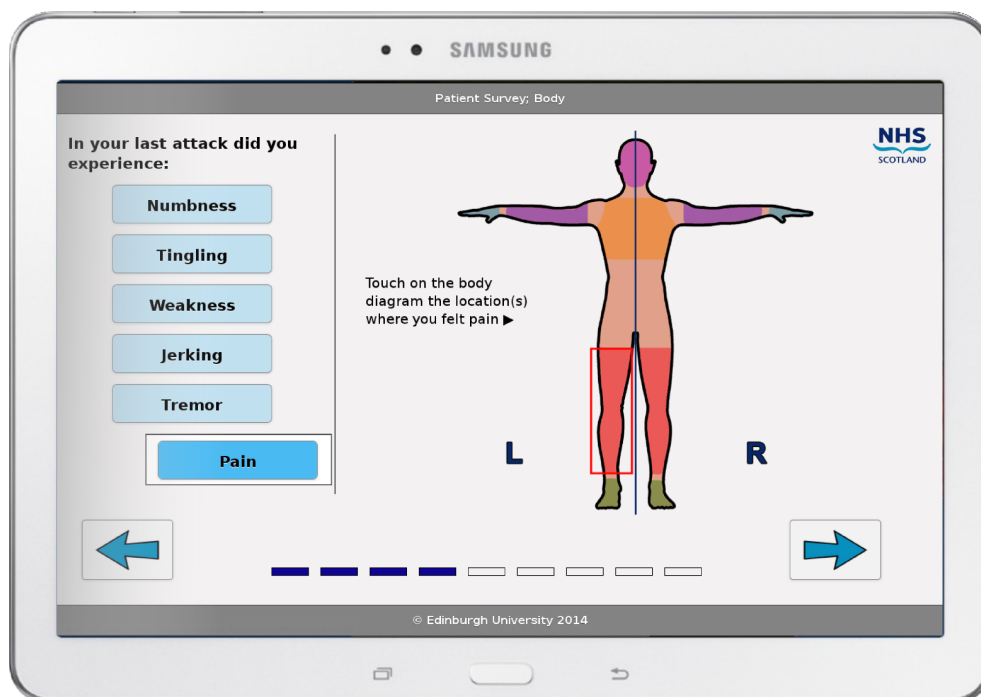


Figure 1.10: An app created using the WAE to help stroke patients communicate their symptoms. Screenshot used with permission of the app's author Helen Mamalaki.

## 1.7 Contributions to knowledge

The thesis contributes to knowledge by offering a critical and reflexive (Finlay, 2002) analysis of the research, design, engineering and socio-technical (c.f. Hughes, 1987) challenges of developing and evaluating medical apps for and with healthcare practitioners. I argue throughout the thesis that concerns related to the lacking quality and credibility of many medical apps cannot be effectively addressed by “market forces” (such as consumer behaviour on app stores), “vetting” by trusted third parties or top-down regulation by governmental bodies with relatively limited resources.

Rather, these issues are symptoms of limitations in the current app commissioning, development and evaluation practices. Drawing on prior work, and using the SBC app as example of how healthcare practitioners, medical students and others contributed quality improvements and helped evidence its usability and efficacy, I suggest that these issues could be overcome by development strategies that promote on-going interdisciplinary teamwork.

Dedicated collaborative app design and evaluation tools, such as the WAE and WAT, can facilitate such strategies, but are still in their infancy. It is also critical to develop and reward the digital skills of healthcare practitioners so that they can become critical consumers of apps and can actively shape the information technologies that they are increasingly reliant on. I will now summarise how the five empirical studies, which contribute to knowledge in several fields (see table 1.6), support this thesis.

Table 1.6: Contributions to knowledge by study and field.

Study	Chapter	Transfusion medicine:	eHealth, tech. assessment & evaluation:	Design, innovation & software eng.:
One	5	✓	✓	✓
Two	6	✓	✓	✓
Three	7		✓	✓
Four	8	✓	✓	✓
Five	9	✓	✓	

**The first study** is a review of an existing transfusion app that aims to support clinicians who are prescribing platelets. It was carried out with seven practitioners in haematology and anesthesiology. The study, among the first independent reviews of an app in transfusion medicine, revealed notable weaknesses in the usability, clinical content and platelet dose calculator. It highlights how medical apps released with bugs and usability problems are not only likely to be rejected by practitioners, but could also contribute to new medical errors. To prevent these issues, it is essential to ensure the budget, training, quality assurance and collaborative processes are in place to detect bugs and roll out fixes in a timely manner.

**The second study** is a qualitative assessment of the SBC prototype. Conducted alongside the first study and with the same participants, the study demonstrates the value of soliciting feedback from healthcare practitioners from different medical specialities early in development. Their critique helped refine the scope, purpose and framing of the project. It also helped improve the content and usability of the app. The

ease of recruiting, coupled with the generous use of their time and interest in the topic, confirmed that engaging healthcare practitioners at the start of the design process is feasible. However, sustaining engagement throughout the iterative design cycle was challenging due to a lack of existing collaborative tools – prompting the third study.

**The third study** concerns the Web App Editor (WAE), the collaborative web-based authoring tool that I created to make it easier to develop the SBC app with others. In this study, I evaluated the editor with students on introductory courses in mobile app development that I taught, and in a Masters project aiming to create an app to elicit symptoms of stroke patients. In these contexts, the WAE enabled users with little prior experience to learn about, create and test mobile apps. Given the right tools and support, even those who are new to app development can acquire the skills to contribute to apps. This extends to healthcare practitioners who should be encouraged to critically analyse and contribute to apps in their area of expertise.

**Study four** is a usability evaluation of the revised version of the SBC app. It was conducted during a blood transfusion training day at a large Scottish University. 54 final year medical students rated the usability of the SBC app as acceptable and their feedback prompted a re-design and expansion of the educational content. The study illustrates the importance of using formative feedback from multiple user groups in the iterative design process. Also, it confirmed the high level of adoption and enthusiasm for mobile devices and apps among medical students and junior practitioners.

Finally, **study five** assessed the impact of the most recent version of the SBC app on practitioners' performance on a knowledge test about the correct use of irradiated and CMV-negative blood. This was a surrogate measure of practice improvement, which unfortunately was infeasible to assess directly (see the start of chapter nine for a detailed discussion). 61 doctors, nurses and biomedical scientists from three Scottish hospitals participated in this online randomised controlled pilot study. The results confirmed gaps in knowledge reported by SHOT and suggested that the SBC app is an acceptable and efficacious learning aid that can enhance practitioners' knowledge. The study also highlights some of the barriers encountered to conduct a study with patient outcomes and demonstrated the feasibility of remotely assessing medical apps with healthcare practitioners using the WAT system.

## 1.8 Thesis outline

This chapter has introduced the research context, aims, rationale, objectives and outcomes. Chapter *two*, the first of two literature chapters, situates the research in the literature on healthcare information technology and the adoption, design and evaluation of mobile medical apps in healthcare.

Chapter *three*, the second literature chapter, provides an introduction to current blood transfusion practice in the UK. It also explains the role of irradiated and cytomegalovirus (CMV)-negative blood in preventing TA-GvHD and TT-CMV.

Chapter *four* is the methodology chapter. It discusses the pragmatic and eclectic research approach necessitated by the interventionist nature of the project. The approach combines concepts from action research, human computer interaction, user innovation theory, healthcare evaluation and software engineering.

Chapter *five* is the first of five empirical studies. It draws on the qualitative evaluation of an existing transfusion app with seven practitioners. Their review of the app, which was designed to support the prescription of platelets, identified several transferable lessons which are discussed in detail.

Chapter *six* presents a formative evaluation study of the SBC app prototype. It explores practitioners' prior experiences of special blood components, views on the causes of mistakes and potential interventions, including the proposed app. Additionally, improvements to the prototype are identified.

Chapter *seven* temporarily shifts focus from the context of blood transfusion to consider how the process of medical app development could be improved. The chapter explores how the Web App Editor, a multi-user app authoring tool, can facilitate digital skills development and effective collaboration during app development in educational settings.

Chapter *eight* is a usability evaluation study of the second revision of the SBC app. 54 medical students, attending a compulsory blood transfusion training day at a large Scottish university, rated the ease of use of the SBC app on the System Usability Scale and offered feedback to identify areas of improvements.

Chapter *nine* is the final empirical study. It assesses the impact of the latest version of the SBC using an online randomised controlled pilot study with 61 practitioners from three Scottish hospitals.

Finally, chapter *ten* analyses the findings of the five empirical studies in relation to previous work and the original research aim. It also discusses the limitations of the research, conclusions and implications for practice and future work.

The bibliography and appendices follows. A glossary of abbreviations and definitions for frequently used terms is also provided (starting on page 371).



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## **Chapter 2: Related work**

This chapter reviews prior work related to the adoption, design and evaluation of medical apps for healthcare practitioners. After describing the methods and scope of the review, I situate it in the wider research landscape by outlining the origins of the study of healthcare information technologies and its socio-technical dimensions.

With this groundwork in place, I then discuss recent studies related to the adoption of medical apps by healthcare practitioners. This is followed by a review of prior work and perspectives on the design of medical apps. The penultimate section discusses evidence underpinning the use of medical apps, methodological and epistemological issues for medical app evaluation, potential risks and the limited success to date of interventions aiming to assure the quality of medical apps. Finally, the chapter concludes with a summary of the key issues and state of research.

## 2.1 Introduction

This review maps key issues associated with the adoption, design and evaluation of medical apps for healthcare practitioners. It is a formidable task as the volume, breadth and rapid development of healthcare information technologies pose considerable difficulties to researchers. This is aptly summed up by Car et al. (2008, 19) who argue that it is “... impossible for any individual to read, critically appraise and synthesise the state of current knowledge, let alone remain up-to-date in this dynamic area”.

As a multidisciplinary area of research, and with contributions originating from the social, engineering and health sciences (figure 2.1), the literature is fragmented. Studies are published in discipline-specific journals, in outlets that cater to niche interests of particular scholarly and medical communities, or in the grey literature where much of the most recent technological development is reported. Cross-cutting journals were only founded relatively recently, such as the 2012 Journal of Mobile Technology in Medicine, and are still in the process of becoming established. The terminology also varies considerably between disciplines (Greenhalgh et al., 2004, 38).

To overcome these issues, I adopted a pragmatic search strategy that borrowed from scoping review methodology (Arksey and O'Malley, 2005). Hence, I searched iteratively using broad keywords to identify relevant systematic reviews, drilling down into individual studies and using back-referencing (snowballing) to identify further relevant work.

In searching the literature, I relied on three main tools: “Discovered”, a service by the University of Edinburgh for searching electronic journals; the US National Institute of Health PubMed database; and the Google Scholar literature search engine. A list of search terms and phrases used is offered in table 2.1.

I have concentrated on literature from the last decade to limit the scope of the review, and to ensure it is up to date with current technologies. As there is a limited amount of recent work from within the transfusion medicine community on the use of mobile computer technology, I also considered work on medical apps from other medical specialties, such as cardiology, dermatology, endocrinology, oncology, microbiology and pharmacology.

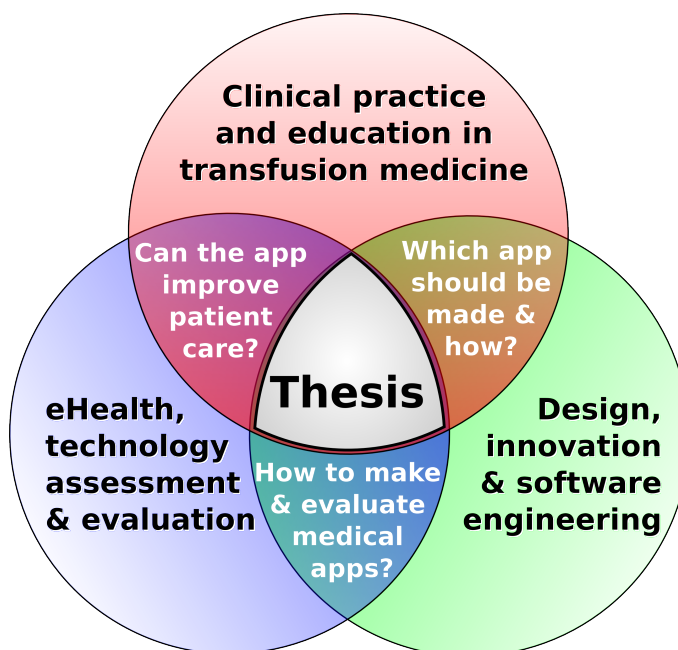


Figure 2.1: Location of the thesis in the related literature.

However, consolidating knowledge from such a wide range of areas is difficult due to the heterogeneity of both the apps under consideration and the (often qualitative) methods employed to review them. There is also a lack of current and comprehensive systematic reviews. Systematic reviews of earlier generations of computer-based interventions, such as those offered by [Car et al. \(2008\)](#) and [Greenhalgh et al. \(2004\)](#), were useful in overcoming some of these issues.

Table 2.1: Terms and phrases used to to identify prior literature.

Theme	Terms
Blood transfusion	BCSH, CMV, errors, guidelines, HLA, irradiated, hotspots, mistakes, near misses, SHOT, SaBTO, statistics, TA-GvHD, transfusion app, transfusion process.
Decision support	accuracy, algorithm, cognitive aids, cognitive biases, computerised decision support, decision tree, frugal decision, heuristics, medical decision making, rule-bound thinking, triage, speed.
General	app, device, ehealth, handheld, mhealth, mobile, smartphone, tablet.
Medical Mobile Apps	adoption, certification, clinical use of apps, contamination, context of use, effectiveness, evaluation, FDA, hacking, hygiene, legal, medical app, medical device, meta, MHRA, mobile medical app, NHS, policy, randomised controlled trial, safety, survey, systematic review, trust, review, regulation, unintended consequences.
Methodology	design, epistemology, ethics, evaluation, human factors, innovation, implementation, methods, mobile app design guidelines, theory, translational medicine, statistics, success factors, usability, user experience, user interface.
Mobile Learning	app-based learning, blended learning, continuing professional development, evaluation, learning design, learning outcomes, medical education, pedagogy, simulation, situated learning, social learning.

As the focus of the thesis is on medical apps for healthcare practitioners, studies of apps for patients and health-conscious consumers have only been considered in passing. Additionally, there are many approaches to design, innovation, medical practice and education, software engineering and evaluation. The purpose is not to provide a comprehensive review of these areas, but rather to map out some of the most relevant issues in relation to the collaborative design of medical apps. To situate recent developments pertaining to mobile medical apps in its broader context, I will now outline the history and scope of the field of healthcare information technology.

### 2.1.1 Healthcare information technology

The modernistic vision of computers as an enabler of efficient and effective healthcare services goes back to the 1950s era of mainframe computers (Kaplan, 1995). Academic interest in the use of computers in healthcare can be traced back to at least 1968 with the founding of the journal *Computers and Biomedical Research* (see table 2.2). Since then the field has expanded in both depth and breadth.

Electronic healthcare or “eHealth” is a relatively new term that only entered into common use after the turn of the millenium (Pagliari et al., 2005). Although the term lacks a succinct and widely agreed definition, it is often used to refer to a wide range of Internet technologies applied within a healthcare context. Perhaps the most widely cited definition is the one offered by Eysenbach (2001, 1):

“e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.”

Mobile medical applications could be classified as a form of eHealth that also belongs to the subfield of mobile healthcare (“mHealth”). As with eHealth, the boundaries of mHealth are imprecise and there are multiple definitions and uses of the term.

For example, mHealth carries connotations to telemedicine – the remote provision of healthcare services through information and communication technologies, such as telephone or video conferencing – as well as the provision of health services in rural areas and in developing countries as part of the ICT for development movement.

Table 2.2: Selected journals in medical informatics by year of first issue.

Journal	Year
Journal of Mobile Technology in Medicine	2012
International Journal of E-Health and Medical Communications	2010
International Journal of Telemedicine and Applications	2008
Electronic Journal for Health Informatics	2006
Journal of Medical Internet Research	1999
IEEE Transactions on Information Technology in Biomedicine	1997
Telemedicine Journal and e-Health	1995
Journal of Medical Systems	1977
International Journal of Medical Informatics	1970
Computers and Biomedical Research	1968

This diverse use of the term could be attributed to the wide applicability of mobile technologies, implicit in the definition of mHealth by [Estrin and Sim \(2010, 759\)](#):

“Mobile communication devices, in conjunction with Internet and social media, present opportunities to enhance disease prevention and management by extending health interventions beyond the reach of traditional care – an approach referred to as mHealth”.

Placing emphasis on the enabling role of mobile technology in healthcare, the World Health Organisation defines mHealth as:

“Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices” ([WHO, 2011, 6](#)).

Studies that fall under the rubric of mHealth cover a wide range of technologies and medical applications ([Klasnja and Pratt, 2012](#)). For example, personal digital assistants (PDAs) in medical education and clinical practice ([Baumgart, 2005](#)), short message service (SMS) for promoting healthy lifestyles in smokers ([Vidrine et al., 2012](#)) and women with young children ([Fjeldsoe et al., 2012](#)), radio-frequency identification (RFID) to reduce patient misidentification ([Thuemmler et al., 2007](#)), miniature computer devices and digital sensors to monitor patients’ vital signs and breathing patterns during sedation ([Kuroda et al., 2013](#); [Drummond et al., 2013](#)), and the use of smartphones to monitor elderly patients with chronic conditions ([Boulos et al., 2011](#)).

Similarly, studies of current generations of medical apps span many application areas, such as the estimation of blood loss during operations ([Sharareh et al., 2015](#)),



detection of hepatitis C (Aronoff-Spencer et al., 2016) and hemolysis (Archibong et al., 2016), medical calculators (Bierbrier et al., 2014) and the development of affordable and portable medical devices, such as electrocardiograms (Chung and Guise, 2015), glucometers (Ramljak et al., 2013) and pulse oximeters (Scully et al., 2013).

These examples illustrate the diverse ways in which mobile technologies may support specific areas of transfusion medicine and general healthcare practice. However, success is contingent not only on narrowly “technical” qualities (which are often stressed), but also on the compatibility with the organisational context of use (Edmondson, 2003; Greenhalgh et al., 2004; Granlien, 2010; Doherty, 2014).

### 2.1.2 Socio-technical dimensions

Since the early work of the 1950s, the understanding of the socio-technical nature of healthcare information technology interventions have evolved significantly (see Berg, 1999). Computer technology is now deeply embedded in contemporary healthcare (Lindsey, 2007, 336). Scholars in the socio-technical tradition view technology as socially constructed and inseparable from the social setting where it is produced (hence the contraction).

It is beyond this chapter to discuss the underpinnings of this perspective and interested readers are directed to seminal works such as Hughes (1987); Winner (1980); Pinch and Bijker (1984); Williams and Edge (1996). Suffice to say that a critical overview

of healthcare information technology cannot ignore the social, economic, cultural and political aspects of the topic. A striking international example of the latter is the approval of the eHealth Resolution by 192 member states of the United Nations in 2005.

Car et al. (2008, 84) argue that the resolution showed “... global political commitment that has translated in unprecedented investment in IT within healthcare”. Hence, healthcare information technologies are interwoven with implicit and explicit visions of the future, and never far from the political limelight. For example, they are often couched in terms of creating more personalised (“patient-centered”) and cost-effective healthcare services, which are highly politicised claims (Kreindler, 2013). To illustrate this using a UK perspective, I will briefly examine projects and policies within the National Health Service (NHS).

Composed of devolved bodies for England, Wales, Scotland and Northern Ireland, the NHS is an important symbol of the British welfare state. It can be dated back to 1942 in Sir William Beveridge’s report *Social Insurance and Allied Services*, and the 1946 *National Health Service Act*. The NHS has since dramatically expanded in both scope and budget (approaching 10% of the UK’s GDP in 2010), and it continues to undergo changes where digital technology plays a significant role (Nuffield Trust, 2012).

For the 65-year anniversary, Timmins (2013) edited a collection of interviews with 65 parliamentarians, officials, health and social care leaders and other commentators, such as clinicians, managers, academics, patient groups and journalists. Although the

accounts are diverse, there are five recurring themes: the challenges of caring for an aging population, technology-based healthcare interventions, efficient resource utilisation, quality of care and patient empowerment.

For instance, people live longer than ever before and this is projected to alter the age distribution of the UK population, as shown in figure 2.2. Such demographic changes have implications for care services as the elderly have more complex and costly healthcare needs due to multiple age-associated chronic conditions (Lehnert et al., 2011). Consequently, there is significant interest in how information and communication

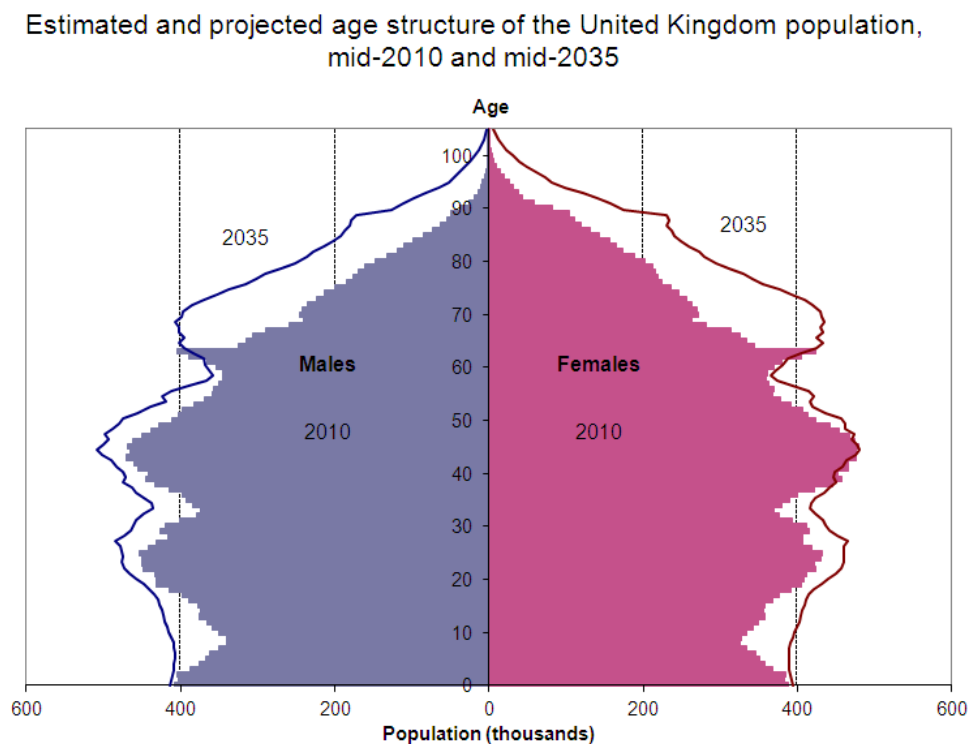


Figure 2.2: Age structure of the UK population in 2010 and 2035. Source: UK Office for National Statistics (2011).

technologies could support the elderly and chronically ill. For example, assistive technologies, robots, remote monitoring and telecare systems aim to enable people to live at home longer and reduce the burden on care homes (Boissy et al., 2007).

Similarly, Living It Up was a project targeting the over 50s, led by NHS Scotland and NHS24, a patient information and self-help initiative. The project aims to “...deliver innovative and integrated health, care and well-being services, information and products via familiar technology ... enabling people to keep better connected with their communities and those they care for and receive care from” (Mair and Lennon, 2015, 3). The project fits with the Scottish government’s eHealth policy for 2011-2017 which justifies investment in IT based on the potential for improving quality and reducing cost (NHS Scotland, 2011).

The Scottish strategy reiterates common claims regarding the benefits of IT, such as: “Making use of information and technology effectively can bring about quality improvements in healthcare services and efficiency savings in healthcare across NHSS. It also crucially frees up staff time for patient care and reduces waiting times.” (NHS Scotland, 2011, 16). This one-sided picture is representative of widely held optimism towards healthcare technology, and echoes the views of the commentators on the future role of technology in the NHS (Timmins, 2013).

While few would dispute that IT is critical to modern healthcare, deterministic views of technology are theoretically unsupported and can disempower marginalised

groups, including women, who are more likely to be on the receiving end of technology projects (Williams and Edge, 1996; Faulkner, 2001; Henwood and Hart, 2003; Lindsey, 2007). When change is attributed to the “inevitable progress of technology”, rather than the social, political, economic and cultural forces that resist or drive such changes, human agency and the option to intervene in change processes is made invisible.

One can disprove determinist claims by pointing at counter-examples. For instance, Wilson (2002) provides a case study where nurses in a large NHS hospital contested the introduction of a computerised care planning system that was designed to reduce the risk of litigation. The nurses who were expected to use the system felt that it reduced patient time and failed to capture the value of their work and skills. The system was eventually scrapped due to the failure to constructively resolve these concerns.

Similarly, failure to engage with healthcare practitioners contributed to the demise of the £12.4 billion NHS National Programme for Information Technology (Npfit). The programme was a government-sponsored megaproject that was delivered by the newly created NHS Connecting for Health agency. Initiated in 2002 to improve the IT infrastructure and to link electronic health records in England (National Audit Office, 2006), the programme carried tremendous political prestige.

While different commentators consider the Npfit a partial success or an outright failure (Cross, 2006; Eason, 2007), it did not deliver on core objectives, ran over budget and behind schedule, and was eventually cancelled in 2011. The Public Accounts Com-

mittee (2011) was highly critical and provided a detailed review of the shortcomings of the project. They highlight issues such as poor consultation with healthcare professionals and inadequate financial and risk management. Furthermore, Coiera (2007) suggests that the NpFIT offers important lessons for areas such as system procurement, patient safety, engagement with clinicians, leadership and evaluation.

These examples illustrate that the impacts of healthcare information technologies are shrouded in political narratives, multifaceted, unpredictable, subjective and rarely carefully investigated (a claim I return to at the end of this chapter). With this brief overview of the broader eHealth research landscape completed, I will now discuss current research on mobile medical apps - starting with work that examines why and how medical apps are used by healthcare practitioners.

## 2.2 Adoption of medical apps

To understand the extent that healthcare practitioners utilise medical apps, their motivations and potential issues that medical app use may give rise to, it is useful to consider the technical, economic, social and cultural changes that have paved the way.

Smartphone and tablet devices have become affordable mass-market consumer electronics that are replacing earlier mobile devices, particularly in emerging markets (Gartner, 2013). These devices can be distinguished from their predecessors by their smaller size, more powerful processors, larger memory, wider range of embed-

ded sensors, increased connectivity options and greater capability to run sophisticated software applications. That said, older generations of mobile phones are predicted to continue to dominate in many parts of the world (Nielsen, 2013).

Current mobile computing devices, such as smartphones, tablets and “wearables” (including “smartwatches”, wristbands, glasses, jewelry and other articles), are incremental innovations (Abernathy and Utterback, 1978) that extend earlier healthcare information technologies, such as computers on wheels, laptops, pagers, personal digital assistants (PDAs) and so on. However, it is not just the shape and features of mobile devices that is evolving, but also the services and networks that underpin them.

With the growth of the Internet and the creation of online app stores, it has become easier to publish mobile software to a large audience. Coupled with the expansion of faster communications infrastructure, this is enabling new ways of creating and distributing software and data in many industries, not least in healthcare (Ofcom, 2014a). Doctors, nurses and other healthcare practitioners rely heavily on computerised information systems to carry out their duties (Reddy and Dourish, 2002, 344). Professional and industry interest in mobile devices and apps thus stems from the utility of accessing medical information via familiar and widely used portable computer technology, and the growing market for such devices and software.

To illustrate the growth and diversity of medical apps, one may consider the great difficulty of identifying and classifying recent work in this area. For example, Mosa

[et al. \(2012\)](#) provides a broad classification of medical apps according to target audience (clinicians; students and patients) and purpose (diagnosis; drug reference; medical calculator; literature search tool and many smaller subcategories). The classification is based on 83 medical apps described in peer reviewed journals. As the number of health-related apps are estimated to have exceeded 165,000 as of September 2015 ([IMS Health, 2015](#)), this is clearly a limited taxonomy based on a very small sample.

Touching on some of the social and cultural issues, the growing use of medical apps by both patients and healthcare practitioners have generated significant media interest. It is an area of research that “makes a good story” as occasionally it borders the realm of cyborgian science fiction. For example, research into biomedical sensors embedded in contact lenses to provide wireless blood glucose monitoring for diabetics ([Yao et al., 2011](#)) was covered in the international press.

Moreover, professional interest is evident by the Royal Society of Medicine’s annual conference on medical apps, now in its fourth year ([RSM, 2016](#)). That said, [Robinson et al. \(2013\)](#) and [Dimond et al. \(2016, 5\)](#) highlight concerns related to the perceived lack of professionalism associated with the clinical use of mobile devices, especially in front of patients. However, other studies suggest that there is a growing use and acceptance of mobile device in the healthcare settings among patients ([Illiger et al., 2014](#)), nurses ([Johansson et al., 2014](#)) and doctors ([Bullock et al., 2015](#)).

Similar concerns and changes in attitude were observed with regards to the adop-



tion of health-related websites following the widespread adoption of the Internet in the late 1990s (Diaz et al., 2002; Cline and Haynes, 2001). The key concern was that the web contained (potentially misleading) medical resources that digitally savvy patients could use to make healthcare decisions. Indeed, Lupton (2014) argues that medical apps could be analysed as socio-technical artefacts produced in the setting of continuing digitisation of medical information brought about by the Internet.

Changes in attitudes toward medical apps could perhaps be explained by the acceptance of mobile devices in the personal sphere, and the rise of distributed professional and patient networks that make use of these technologies. For example, Masters et al. (2016, 538) argue that the distinction between using a medical app for education and clinical practice is blurring as mobile devices are used daily to carry out a wide range of work and domestic tasks. So how are apps used in clinical practice?

### 2.2.1 Clinical use of mobile devices and apps

Healthcare practitioners' ownership and use of medical apps have been explored in several surveys. For instance, Mobasher et al. (2015) investigated the use of smartphones and tablets among 287 doctors and 564 nurses in five hospitals in a single NHS Trust. Over 95% of the responding doctors and nurses owned a smartphone, and 50% of doctors reported using their smartphone instead of a bleeper. Nearly 80% of doctors also owned a medical app, and of these 90% said that they used it in their practice.

The study also found that medical app ownership and use was lower among nurses (35% owned medical apps, of which 67% reported using it in their work). There is a need for more work exploring nurses' use of mobile devices, although it is possible that some of these differences in self-reported use could be attributed to the gendered nature of care and technology work (Lindsey, 2007). For example, Hardyman et al. (2013) found that smartphone usage was more frequent in male junior doctors ( $p < 0.01$ ).

In a survey of 76 surgical trainees in Scotland, Carter et al. (2014) found that nearly all owned a smartphone and over half reported using it to access medical apps in their practice. The apps included guidelines, calculators, anatomical references and study guides. Seven of the participants had noted errors in the outputs of medical apps, adding to concerns over lacking quality (discussed at the end of the chapter).

In another small study, O'Reilly et al. (2014) surveyed smartphone ownership and the clinical use of apps among 61 junior doctors at two Irish university hospitals. Again, almost all reported owning a smartphone and using it on-call for a variety of purposes, such as to aid in diagnosis, dose medications, find interactions between medications and to access medical emergency protocols.

Additionally, many of the junior doctors felt that having a smartphone improved their efficiency, time management, communication with patients, confidence, level of knowledge and safety. They also felt that it reduced stress and the need to ask for help from senior colleagues. Although there is little strong published evidence to support

this belief, the smartphone was perceived by new doctors as an important tool that improve their ability to carry out their responsibilities with confidence.

This view is, however, supported by work undertaken by [Bullock et al. \(2015\)](#), discussed in detail in the later section on medical education. They found that junior doctors transitioning into new roles used medical apps to resolve difficult clinical cases and that this resulted in improved patient outcomes. Medical app use was also associated with greater engagement with senior colleagues, suggesting that mobile technology influences interprofessional relationships, such as those between junior and senior staff. However, medical apps can be used in unintended ways - a notion known as “interpretive flexibility” ([Pinch and Bijker, 1984](#)) - making it difficult to predict their outcomes on patient care without further quantitative and qualitative research.

In one of the largest studies of clinical smartphone use, [Franko and Tirrell \(2012\)](#) surveyed 3306 students and doctors attached to the Accreditation Council for Graduate Medical Education in the US. 85% of respondents owned a smartphone and about every other respondent reported that they used it in their clinical practice. They also reported that respondents felt that there is a lack of high quality apps, especially for medical textbooks and treatment algorithms. This suggests that there is demand for high quality clinical decision-support and learning materials in the form of apps.

Finally, in one of the first major studies of medical smartphone use in the UK, [Payne et al. \(2012\)](#) surveyed 257 medical students and 131 junior doctors. They found

that just under 80% of respondents owned a smartphone. This was a higher rate of adoption than the population at large at the time<sup>1</sup>. Most respondents had between one and five medical apps installed on their smartphones and reported using them several times every day, but for less than 30 minutes per day. The study concluded that medical students and junior doctors are demanding more apps that could support their medical education and clinical practice.

Perhaps encouraged by the demand of medical professionals and the potential to increase the dissemination of their guidelines, several professional medical bodies have now published apps intended to be used by healthcare practitioners in clinical decision-making.

### 2.2.2 “Appification” of medical guidelines

Medical decision-making is a critical process that is influenced by cognitive processes and biases (Stiegler and Tung, 2014). The use of evidence-based medical guidelines and heuristics can lead to better decisions (Grimshaw and Russell, 1993; Gigerenzer and Kurzenhauser, 2005; Marewski and Gigerenzer, 2012). However, Tanenbaum (1999, 762) argues that standardised medical guidelines challenge the experiential knowledge of health professionals and may promote detrimental rule-bound thinking. There are also issues associated with disseminating and promoting the use of medical guidelines,

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<sup>1</sup>In 2013, less than two-thirds of UK adults owned a smartphone (Google/Ipsos, 2013), and only about 25% owned a tablet device (Ofcom, 2014b)

such as raising awareness and changing existing practices (Lugtenberg et al., 2009).

The portability, searchability and the ease of distributing and keeping information updated through mobile apps could potentially improve the dissemination and use of medical guidelines. Charani et al. (2013) offers data, collected from the adoption of an app with the antibiotics policy of the Imperial College Healthcare NHS Trust, which lends some support to these assertions. The Imperial Antibiotics Prescribing Policy (IAPP) app was promoted at several teaching sessions for junior doctors, via an email and on the Trust's intranet and newsletter. Within one month, 40% (374) of junior doctors had installed the app. By twelve months, it was adopted by all (990) junior doctors. User tracking suggested that the app was being accessed ten times more frequently than the existing intranet version of the policy, and 81% of a sample of 59 doctors felt that the app helped them adhere to the Trust's policy.

This adaptation (or “appification”) of guidelines into app format is well under way in other areas too. For example, all trust-approved hospital guidelines at the Nottingham University Hospital (NUH) are available as an app.<sup>2</sup> Furthermore, apps based on national evidence-based guidelines have been published by bodies such as the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), the Royal College of Obstetricians and Gynaecologists (RCOG) and the British Society for Haematology (BSH).

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<sup>2</sup><https://www.nuh.nhs.uk/nuh-guidelines-app/>

### 2.2.3 Mobile learning in medical education

Another area where apps have made inroads is in medical education. Popular medical textbooks are widely available on mobile devices and [Davies et al. \(2012\)](#) trialled the use of handheld iPAQ PDAs preloaded with reference textbooks among medical students. Nearly 400 undergraduate medical students at a UK medical school took part in the study, which was based on survey data and four focus groups.

Although the survey response rate was low, about half the students reported using the devices at least weekly to access reference materials, such as drug and anatomy textbooks. Barriers to mobile learning identified by students included negative attitudes from colleagues towards using the devices on the ward, poorly designed and unreliable technology, and the need to carry another device. Many participants also expressed a preference for using a smartphone instead of a PDA.

In line with [Traxler \(2007, 7\)](#), the authors argue that mobile devices can enable situational and “just in time” learning, and offer freedom to access resources in the home or workplace place during low demand. The utility of smartphone devices in medical learning has also been demonstrated in the Welsh “iDoc” initiative ([Hardyman et al., 2013](#); [Bullock et al., 2015](#); [Dimond et al., 2016](#)). iDoc is a smartphone app which provides off-line access to a selection of popular medical reference textbooks.

The app was first made available to Welsh junior doctors in 2009 through the Wales Deanery and remains actively promoted, for example through the website.<sup>3</sup> The iDoc

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<sup>3</sup><http://idoc.walesdeanery.org>

initiative is notable for its evaluation focus. The Cardiff Unit for Research and Evaluation in Medical and Dental Education has evaluated the initiative repeatedly and have furthered understanding of how junior doctors make use of apps in their practice.

Hardyman et al. (2013) offer qualitative evidence from real clinical situations encountered by junior doctors suggesting that the iDoc app enabled more expedient pain management and assessment of patients. The app was also used to facilitate ad hoc teaching and learning between patients and staff, for improving communication between practitioners, and for flagging up complications during care planning.

Despite these positive outcomes, app-based textbooks and educational materials are not supported and evaluated at an institutional level in many areas of medical education. For instance, desktop-based e-learning systems have dominated blood transfusion education in the UK (Graham, 2015; Smith et al., 2014, 2011).

In the US, some medical schools have been early adopters of mobile devices in the curriculum. For example, at the University of Utah, the Health Sciences Library have supported the use of mobile devices since 2003 (Le Ber and Lombardo, 2012, 151). Similarly, one year after the first release of the Apple iPad tablet in 2010, the Yale School of Medicine started providing their students with individual iPads and mobile apps in an effort to move towards digital curricular delivery and to reduce paper waste (Skomorowski et al., 2013, 22).

Other US institutions have since followed their example, and between 2011 and

2012 all 119 residents at the Riverside Methodist Hospital were provided with iPads. However, a survey of the clinical and educational utility of the iPads answered by 102 of the residents (86% response rate) found that the utility was low, partly due to connectivity and technical problems (Skomorowski et al., 2013, 22).

US medical libraries have also explored the use of apps in learning and research. For instance, the Pennsylvania Hospital Library provided iPads to patrons and analysed the use of apps by clinicians for information seeking and patient education (Witman, 2012). Similarly, the Mobile Technology Team at the University of Florida Health Science Center Libraries have examined how they can support healthcare professionals' use of mobile devices and apps (Bushhousen et al., 2013, 67). In a study of 432 patrons, they found that over 40% of respondents used apps to support their clinical duties, such as looking up drug information or accessing journal articles (Bushhousen et al., 2013).

Furthermore, nearly all respondents expressed a desire for a list of vetted or quality assured apps, suggesting a possible future role for medical libraries (Bushhousen et al., 2013, 66). Other studies have also discussed the difficulty for practitioners to identify and decide on which apps to use (Wiechmann et al., 2015; Aungst et al., 2014; van Velsen et al., 2013). Developing external review mechanisms to quality assure medical apps is an issue that I return to at the end of the chapter. However, quality assurance could also be viewed as an integral part of the design process and I will now consider prior work relevant to the design of medical apps.



## 2.3 Design of medical apps

Weaknesses in healthcare information technology and medical apps are frequently attributed to limitations in the design process, such as failure to engage sufficiently with users and medical experts, and to conduct and learn from timely evaluation research (Pagliari, 2007; Car et al., 2008; Masters, 2014; Visvanathan et al., 2012; Hamilton and Brady, 2012; Haffey et al., 2013b; O’neill and Brady, 2012; Zhou et al., 2012).

What design work entails, and who is qualified to carry it out, is contested. The study of design is fragmented (Margolin, 1989, 5) and attempts at narrowly defining design may serve the interest of “professional” designers and exclude others – an activity known as “boundary work” Gieryn (1983). In contrast, the definition by Simon (1996, 111) argues that design is a process common to many professions:

“Everyone designs who devises courses of action aimed at changing existing situations into preferred ones. The intellectual activity that produces material artifacts is no different fundamentally from the one that prescribes remedies for a sick patient or the one that devises a new sales plan for a company or a social welfare policy for a state. Design, so construed, is the core of all professional training...”

According to this definition anyone with expertise relevant to a problem, including patients and healthcare providers, could participate in design, regardless of whether the end product is an app or another product. This perspective underpins the view that users should be encouraged to participate in the design of healthcare information technologies (Berg, 1999). For example, Car et al. (2008, xxvii) argue that user engagement is critical throughout the development of healthcare information technologies:

“End-user consultation and feedback should be viewed as an on-going process and should therefore continue after deployment to ensure that problems are identified early [and] solutions [...] can be incorporated into system upgrades.”

However, many app developers appear to be out of touch with their users. In a survey of over 3000 international app developers, only one quarter reported that they planned apps in discussions with their customers (Vision Mobile, 2013a). Furthermore, app stores are geared toward consumption and discovery of apps, rather than two-way communication and collaboration between developers and users (Pagano and Walid, 2009). Interactions are typically limited to downloading, leaving comments and rating apps. One approach to improve the quality of medical apps is then to make development processes more open and collaborative to encourage healthcare practitioners to become active participants or even take the lead during the design process.

### 2.3.1 User-centered design, lead users and co-design

Involving users in the development process is at the heart of user-centered design (UCD). UCD is an approach to software development that can be traced back to the 1960s socio-technical systems approach (Ritter et al., 2014, 41). It advocates close collaboration between software developers and users to ensure that the resulting product aligns with the needs and capabilities of users and the context in which they operate (Kling, 1977; Norman, 1988).

There is a substantial UCD literature with several schools of thought and contin-

uing debate about how to best apply UCD principles, not least in the creation of new applications using contemporary web and mobile technologies (Williams, 2009; Peischl et al., 2015). Lawler et al. (2011) includes user-centered design among ten human factors recommendations for improving the design of healthcare information technologies. The recommendations are applicable to medical apps and also emphasise software testing, training, risk assessment, continuous improvement and evaluation, anticipation of future needs, effective workplace configuration and system usability.

Complementing UCD, work in innovation studies have demonstrated that companies can benefit from identifying, learning from and involving so called “lead users” in the design process (von Hippel, 1986). These are advanced users who are well-placed to contribute to new products because they have an unmet need, intimate knowledge of the context of use, and have often started to design a solution to resolve the problem.

In a medical context, lead users can be patients (Oliveira et al., 2015), nurses, doctors (DeMonaco et al., 2006) and others. Another common label for a process where users and developers work together to create a product is “co-design”. Sanders and Stappers (2008) traces the history of co-design back to earlier work in user-centered design, arguing that role of the “professional designer” is shifting towards that of a facilitator and researcher.

The changing relationship between the user/consumer and designer/producer is further analysed by Humphreys and Grayson (2008, 1) who argue that “‘co-creation’,

‘co-production’, and ‘prosumption’ refer to situations in which consumers collaborate with companies or with other consumers to produce things of value”. However, facilitating user collaborations can be difficult and there are few studies of how to apply such principles in practice (Ram et al., 2007, 69). In the context of online consumer health information, Norman and Skinner (2006, para. 1) argue that digital literacy skills (or “eHealth literacy”) is critical to reap the benefits of technology:

“Electronic health tools provide little value if the intended users lack the skills [...] Engaging with eHealth requires a skill set, or literacy, of its own.”

This argument could readily be extended to healthcare practitioners. Digital skills are vital to assess the quality of medical apps and to allow healthcare practitioners to become critical consumers of medical apps (Haffey et al., 2013a). Such skills are also necessary to enable practitioners to become active contributors to medical apps, and healthcare information technology more generally (Henwood and Hart, 2003, 264).

In Denmark, Thorell et al. (2015) surveyed 8000 medical students at the University of Copenhagen to understand how they used information technologies, and whether they felt that they were taught sufficient ICT skills during their training. Of the 1165 students who responded (12% response rate), over half expressed interest in additional training to ensure they acquired the ICT skills required in their profession.

In addition to facilitating skills development, the use of appropriate tools and methods is important for effective collaboration. von Hippel (2001) discusses how “user innovation toolkits”, including computer aided design software applications, have lead

to new products in many industrial sectors. These are tools that make it easier for users to create or customise products that suit their needs.

Collaborative software tools have been pioneered in the free libre/open source software movement. For instance, *Git* is a distributed version control system that provides an effective way of handling changes to files made by multiple authors. It was created to facilitate cooperation on the GNU/Linux operating system kernel, which is embedded in mobile devices and Internet infrastructure (Perez-Riverol et al., 2016, 1).

Used by millions of projects, Github.com is a web-based service that extends *Git* by offering social networking and community features (Ram, 2013). Dabbish et al. (2012) interviewed 24 Github users and concluded that the service can improve collaboration, innovation, transparency and learning in knowledge-based projects. Similarly, Ram (2013) argues that Github could improve reproducibility and transparency in research. The core tenet of the free/libre open source movement - enshrined in its license agreements - is that collaboration is more effective when resources, such as source code, are made freely available for use, modification and reuse (an argument expounded in Eric Raymond's seminal book *The Cathedral and The Bazaar*).

However, open source tools and principles have so far had limited impact on health-care software outside of niche areas (Janamanchi et al., 2009), although this may be changing (Benson, 2016). For example, Perez-Riverol et al. (2016) provides ten rules for improving collaboration practices in bioinformatics using *Git* and GitHub. Addition-

ally, as the number of available medical apps are growing and the market is becoming difficult to navigate for consumers, [van Velsen et al. \(2013\)](#) argue that there is a need to develop a collaborative open source model to coordinate efforts.

While participative methods and tools could enable co-design and user innovation in healthcare, such initiatives have faced barriers, including existing power relationships, resistance to change and the drive for standardised healthcare ([Batalden et al., 2015](#)). However, there are examples of projects where medical students and healthcare practitioners have been supported to learn about and develop medical apps ([Masters, 2014](#); [Youm and Wiechmann, 2015](#)).

These studies also show that it is important to inspire and empower practitioners to become interested in the topic, as they may otherwise feel that they lack the motivation, confidence and technical skills to get involved ([Lindsey, 2007](#); [Henwood and Hart, 2003](#)). Safe spaces for learning and experimentation, such as NHS Hackaday<sup>4</sup>, could promote participative design in healthcare. Having explored the opportunities and challenges associated with more participative and open approaches to medical app design, I will now attempt to draw lessons from previous apps and design guides.

### 2.3.2 Case studies and design guides

There is a shortage of studies and systematic reviews that investigate how medical apps are, or should be, designed at a generalisable level. However, there is a growing

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<sup>4</sup><http://nhshackday.com/>

number of studies which report findings from the design of specific medical apps. I will briefly consider design lessons from three such studies, related to apps intended to aid prescribing, decision support and care planning.

The National Centre for Infection Prevention and Management (CIPM) developed a smartphone application to promote restrictive antibiotics prescription ([Imperial College, 2012, 2013](#); [Charani et al., 2013](#)). After establishing the need for the app, the authors developed it and promoted it as part of a broader initiative to improve antibiotics prescribing. One of the design challenges they encountered was that it was difficult to push updates after the app had been installed by users and when new guidelines became available. They also identified a range of cultural, technical and individual barriers to adoption, such as organisational policies which restrict the use of mobile devices in hospital environments.

Moreover, [Yuan et al. \(2013\)](#) discusses the design of an app aiming to provide acute care decision support for nursing staff to identify patients who are deteriorating (a topic explored in a PhD thesis at Sheffield University by [Stevenson, 2016](#)). They conducted usability evaluation based on violations of Nielsen & Molich's 1990 user interface heuristic, task completion and timing, and the NASA Task Load Index. The authors concluded that the design of the app's user interface is fit for purpose. However, they also acknowledge that training and cultural acceptance remain important (and at the time of the paper outstanding) aspects to address to ensure uptake.

Adopting an iterative development process involving a cross-functional team of experts in medicine, ergonomics and software engineering, Ehrler et al. (2013) describes the creation of an app intended to enable nurses to plan their daily workload. The authors identify and propose solutions for several challenges facing medical app designers, including financial constraints, hardware limitations, interoperability with healthcare systems, data security and usability.

For example, they highlight the need for clear governance to overcome the inherent conflict between the typically “cheap and cheerful” approach associated with consumer mobile apps and the requirement in medicine for reliable and high quality software. The authors also offer recommendations for ensuring a high degree of usability in medical apps and reducing the likelihood of user error by having a predictable and familiar user interface that structures information sensibly.

In summary, although the examples are diverse and context-specific, studies of this kind are useful for informing future work. They offer lessons that can preempt unforeseen challenges. They can also help identify methods for assessing apps and provide suggestions for how barriers could be overcome. However, it is hard to consolidate knowledge from individual studies and there are few systematic reviews. Medical app development guides that aim to promote good design practices could help fill this gap.

Unfortunately, the availability and quality of current guides is limited. One of the most extensive resources targeting those interested in medical app development in the



UK is the 2014 *NHS Guide for Developing Mobile Healthcare Applications* (NHS Innovations South East, 2014). Following a linear eight-step medical app development process, the guide spans pre-development, design and development, user testing, stakeholder review, medical device approval and deployment to app stores through to marketing and “monetisation” (i.e. a discussion of different business models for medical apps).

The guide is a useful and easy to use introductory resource for gaining an overview of the medical app development process. However, it does not address the importance of planning and budgeting for software maintenance and evaluation research. It also provides little in-depth advice for anyone who are looking to resolve technical questions or issues related to evaluation methodology. For example, the guide does not help to answer questions such as which technical framework to use or what might be appropriate evaluation methods and endpoints.

Another perspective on the medical app development process is offered by Johnston et al. (2015) who have proposed the “CDE” model. It involves three steps, each corresponding to a letter of the abbreviation: C - Clarify the task; D - Design the app; and E - Evaluate it. While it is a simple to remember acronym that places emphasis on key aspects, such as evaluation, the model could be criticised for adopting an incomplete and non-iterative bird’s eye view of the development process.

For example, it omits key steps in the app life-cycle, such as bug fixing or promotion. It also does not consider the importance of broader socio-technical issues, such as

securing clinician and management support. Naturally, the development of a medical app is not just concerned with the look or feel of the final product – aspects treated in generic mobile app design advice offered [Google \(2015\)](#) and [Apple \(2015\)](#) – but also the way in which it is promoted and implemented in the workplace.

### 2.3.3 Implementation design and organisational change

Good product design - characterised by ease of use, high task completion, appealing aesthetics and pleasure from use - is important but insufficient to ensure the uptake of healthcare innovations ([Greenhalgh et al., 2004](#); [Silverstone and Haddon, 1996](#)). This insight has prompted [Karsh \(2004\)](#) to develop what he calls “implementation design principles”. These emphasise the importance of creating a structured implementation approach or “roadmap” to ensure appropriate training programmes, pilot testing, management support, organisational communication structures, feedback and other aspects are in place to ensure a successful adoption process.

A concrete example is offered by [Murphy et al. \(2009\)](#) who provide a detailed account of the development and staged implementation of an end-to-end electronic transfusion system in three hospitals in Oxfordshire over the course of ten years. They identify several critical success factors, such as time, resources and expertise, teamwork, staged implementation, management and clinician support, investing in training and a determination to overcome organisational issues and technical problems.

Table 2.3: Aspects influencing the adoption of healthcare innovations, adapted from [Greenhalgh et al. \(2004, pp. 13-15\)](#).

Aspect	Desirable properties and circumstances
1. Relative advantage	Clear effectiveness advantage recognised by all key players.
2. Compatibility	Match the norms, values and perceived needs of adopters.
3. Complexity	Simple to use.
4. Trialability	Easy for users to try out and experiment with.
5. Observability	Benefits are visible to the users.
6. Re-invention	Modifiable by the adopter to fit their needs.
7. Task relevance	Relevant to the user's work responsibilities.
8. Task usefulness	Improves the performance of the user.
9. Feasibility	Workable in the intended setting of use.
10. Implementation	Can be used immediately without overcoming barriers.
11. Divisibility	Support incremental adoption.
12. The nature of the required knowledge	Implementation knowledge is codified and transferable to new settings.

Similarly, [Edmondson \(2003\)](#) analysed the introduction of new cardiac surgery technology in four hospitals. The study shows that the success of the implementation was contingent on team work, dynamic leadership and a framing of the project as learning journey that involved trial and error. Moreover, [Greenhalgh et al. \(2004\)](#), extending the Diffusion of Innovation Theory ([Rogers, 2003](#)) to health services organisations, have identified key factors influencing the uptake of healthcare innovations (summarised table 2.3). They place particular emphasis on ensuring user acceptance (items 3, 4, 5, 7, and 8 in the table) and achieving a good “fit” between the innovation and the organisational setting of use (items 1,2, 9 and 10).

Furthermore, [Berg \(1999\)](#) argues that the implementation of healthcare information technology is a political process of organisational change. This process is “messy” and defies simplistic linear accounts. Rather it requires “...an iterative approach, in which the distinctions between ‘analysis’, ‘design’, ‘implementation’ and ‘evaluation’ blur” ([Berg, 1999, 87](#)). Hence, the widespread notion of an upfront “design” phase is misleading as design work continues during the implementation process. For example, design work may take the form of healthcare practitioners coming up with “workarounds” to ensure electronic healthcare record systems better meet their needs ([Berg, 1999, 97](#)).

This continuation of design during implementation has been labelled “innofusion” (a contraction of innovation and diffusion) by [Fleck \(1994, 638\)](#). The notion extends domestication theory, which highlights the work that users carry out to make sense of and incorporate innovations in their lives ([Silverstone and Haddon, 1996](#)).

Finally, formative evaluation plays a critical role in the development of eHealth interventions ([Granlien, 2010, 49](#)). Separating “evaluation” from “design” is thus a false dichotomy as these activities are closely related and ideally feed off one another, although they of course also compete for limited resources ([Pagliari, 2007, p.5](#)):

“... economic drivers prioritize the production of resources that meet key functionality criteria and client-defined requirements within commercially viable time frames. Evaluation often takes a lower priority, and rapid application development using small convenience samples of users is common”

However, one cannot neglect one activity over another other because as [Craig et al. \(2006\)](#) argue there is a need to balance all stages of the process:

“Developing, piloting, evaluating, reporting and implementing a complex intervention can be a lengthy process. All of the stages are important, and too strong a focus on the main evaluation, to the neglect of adequate development and piloting work, or proper consideration of the practical issues of implementation, will result in weaker interventions, that are harder to evaluate, less likely to be implemented and less likely to be worth implementing.”

I return to this tension between design and implementation versus the need to generate strong evidence by conducting rigorous evaluations in in chapter four. I will now turn to the evaluation of medical apps, relating it to prior work on evidence-based medicine, risk management, quality assurance and regulation.

## 2.4 Evaluation of medical apps

Evaluation has connotations to a wide range of critical issues related to medical apps, including evidence-based medicine (should apps be used in medical practice?), research methodology (how should apps be evaluated?), risk management (how should apps be risk assessed?) and regulation (how should apps be regulated?). I will begin by giving an account of the state of current evidence for medical apps.

The clinical use of medical apps has sparked considerable debate because most lack strong supporting evidence (Boulos et al., 2014; McCartney, 2013; Buijink et al., 2013; Kamerow, 2013; Ozdalga et al., 2012; Nolan, 2011). Furthermore, studies have identified weaknesses in medical apps intended to be used by professionals in specialties such as cardiology (Kumar et al., 2015), dermatology (Hamilton and Brady, 2012), en-

ocrinology (Eng and Lee, 2013), microbiology (Visvanathan et al., 2012), oncology (Bender et al., 2013; Wolf et al., 2013), pharmacology (Haffey et al., 2013a,b), urology (Pereira-Azevedo et al., 2015) and women's health (Derbyshire and Dancey, 2013).

For instance, Hamilton and Brady (2012) reviewed 79 dermatology-themed apps and found that only 20 disclosed the authors' medical qualifications. While acknowledging the potential of apps for improving dermatology practice – for example by applying vision algorithms to classify skin pigmentations – the authors expressed concern over apps that claim to diagnose skin lesions and offer a false sense of security. The authors call for more transparent disclosure of the app creators, and for external quality review processes to guarantee the accuracy of the apps.

Haffey et al. (2013b) reviewed mobile apps that aid opioid prescription. They assessed 23 apps intended to support dose conversion when switching between opioids, using criteria such as output dose recommendation and the level of professional medical involvement in the design. In this study, about half the apps clearly signaled professional medical involvement and referenced sources.

Additionally, eight apps did not warn the user about dose reductions, which is a standard practice when switching opioid. The study authors call for stronger regulation of medical apps to prevent potential harm to patients. Similarly, Visvanathan et al. (2012) reviewed 94 apps in microbiology. They found that only one in three provided information about the medical expertise of the authors or contributors, once again

raising questions about the quality of the medical content.

In a subsequent review of drug prescription apps more generally, [Haffey et al. \(2013a\)](#) analysed over three hundred apps (including “appified” medical textbooks). They concluded that there are medical apps that could potentially improve prescription practice, but that the medical expertise of the app developers must be made available so that clinicians can make informed choices about which apps to use.

[Pereira-Azevedo et al. \(2015\)](#) conducted a systematic review of 150 urology apps for Android and iOS devices. Their findings mirror the previous studies in that a significant portion of apps lacked evidence of healthcare professional input. Only just over one third of apps were developed by a scientific urology association. To address this issue, [Pereira-Azevedo et al. \(2015, 2\)](#) suggest that “... urologists become stakeholders in mHealth, shaping future app design and promoting peer-review app validation.”

Studies of apps for patients also offer important lessons. For example, [Kumar et al. \(2015\)](#) reviewed 107 apps for self-management of hypertension. They found that 14% purported to provide reliable measure of blood pressure, yet none of the apps used a blood pressure cuff or other validated method for measuring blood pressure.

Diabetes is a popular topic for self-help apps and [Demidowich et al. \(2012\)](#) conducted a review of 42 Android apps intended to help diabetics manage their blood sugar, medications and insulin doses. Two evaluators scored each of the apps independently according to features and usability criteria. The apps were ranked and the

authors concluded that clinicians may want to recommend the top ones to patients.

Likewise, [West et al. \(2012\)](#) reviewed a wide range of apps aiming to enhance public health through exercise, healthy eating and other positive behavioural changes. They evaluated the apps against the Precede-Proceed Model of behaviour change, finding that few apps address all stages recommended for behavioural change (predisposing, enabling, and reinforcing), and therefore are less likely to be effective.

Finally, [Eng and Lee \(2013\)](#) analysed endocrinology apps intended for either patients or healthcare practitioners. They found several insulin calculator apps that would be classified as medical devices, but which lacked any indication of having gone through FDA regulatory approval. Additionally, they concluded that “... it is certainly possible that use of these apps could lead to adverse events.” ([Eng and Lee, 2013, 6](#)).

Although studies such as the above are useful in gaining an overview of currently available apps, one limitation is that they tend to consider a large number of apps relatively shallowly. There is a shortage of peer reviewed evaluations that examine a smaller number of apps in greater depth, and that are written by authors who are independent from the development team.

One exception, however, is the study by [Morris et al. \(2013\)](#). They conducted a small RCT to evaluate two competing smartphone apps for calculating fluid replacement in burns victims. 34 trainee and consultant surgeons in Burns and Plastic Surgery, anaesthetists and nursing staff were asked to carry out simulated fluid calculations



using a standard calculator, the “uBurn” app and the “Mersey Burns” app.

No significant difference was discerned between the interventions in terms of the accuracy of the calculations or the ease of use. However, participants completed the calculations quicker when using the apps. The authors therefore concluded that both apps are suitable for clinical use. The Mersey Burns app is also one of the first apps that have been registered as a medical device in the UK.

The lack of evidence of the effectiveness of medical apps extends to other health-care information technologies. The report entitled *The impact of eHealth on the quality and safety of healthcare* (Car et al., 2008) was the culmination of an ambitious research project investigating the impact of eHealth interventions. Having reviewed 284 randomised controlled trials and 67 systematic reviews, the authors concluded contrarily:

“... eHealth applications have the potential to dramatically improve the quality of healthcare delivery [...] [and] the safety profile of medicine through elimination of both latent and active errors [—] The major finding from reviewing the empirical evidence - which is of variable quality - however, is that there is very limited rigorous evidence demonstrating that these technologies actually improve either the quality or safety of healthcare.” (Car et al., 2008, xxv)

A lack of evidence does not imply that use is necessarily inappropriate however. There are multiple reasons why good evidence about the impacts of eHealth interventions is lacking. Car et al. (2008, xxvi) have identified several causes, such as a general lack of primary research, serious methodological flaws and failures to consider the socio-technical context of healthcare information technology projects. Furthermore, high quality evaluations of eHealth interventions can be time-consuming, expensive,

difficult to conduct and may rank low on the agenda. The evaluation of healthcare information technologies also raises methodological and epistemological challenges.

### 2.4.1 Methodological and epistemological issues

Understanding the consequences of medical interventions, including computer-based interventions, is a central concern for medical research. Evaluation research is necessary to assess the impact of interventions. There are ample examples where such research has established that previously accepted medical practices have caused more harm than benefit, such as with the routine use of corticosteroid in adults with head injury (CRASH trial collaborators, 2005). Conversely, research has strengthened the evidence for the effectiveness of treatments. For instance, the use of tranexamic acid, a cheap and widely available drug that improves blood clotting by preventing the breakdown of fibrinogen, has been demonstrated to reduce mortality in bleeding trauma patients (Roberts et al., 2011, 2010).

These examples illustrate that, like Popperian science where knowledge takes the form of conjectures which are upheld until falsified (Miller, 1983), medical practice is tentative and must be revised in line with new scientific evidence. A dominant thought in western medicine embodies this principle. Evidence-based medicine (EBM) is “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (para. 3 Sackett et al., 1996).

While the core principle underlying EBM paradigm is sound, it is not unproblematic (Greenhalgh, 2014) and dogmatic insistence on published evidence from randomised controlled trials (RCTs) have been parodied (Smith and Pell, 2003). Furthermore, there are concerns over publication bias and there have been calls to increase transparency in clinical trials given the substantial commercial interests at stake when developing new drugs and treatments (Dunn et al., 2012).

There are also criticisms pertaining to the hierarchical rating systems, such as GRADE (GRADE working group, 2013), that are used in evidence-based medical guidelines and systematic reviews (Cochrane, 2013) to rank the quality of available scientific evidence. These systems enable judgements to be made between observational studies, usually more qualitative in nature, and quantitative studies, such as randomised controlled trials (RCTs).

RCTs are resource-intensive, difficult or even impossible to apply to certain problems and are largely incompatible with the interpretivist research paradigm (Treasure, 2009; Smith and Pell, 2003; Rees, 2000, 2002, 2008, 2010; Wadman, 2013). For example, Treasure (2009) argues that surgeons rely on knowledge accumulated on a case to case basis which cannot be easily demonstrated using randomised controlled trials. Similarly, evaluating eHealth interventions is very different from evaluating a drug.

Identifying the most appropriate way to evaluate computer-based interventions is difficult and contentious. Assessing the impact of eHealth interventions using RCTs is

thus not always possible and risks missing the significance of context-specific aspects of the intervention, such as their uptake in actual workplaces:

“Systematic reviews of RCTs [randomised controlled trials] are, on account of their ability to control for known and unknown confounders, the "gold standard" evidence source in relation to studying the effectiveness of interventions. Whilst RCTs and systematic summaries of these are ideally suited for studying drug treatments, they are [—] unable to shed detailed insights on whether systems will be used or indeed how they will be used - factors which greatly influence the effectiveness (as opposed to efficacy) of interventions when implemented in routine practice.” (Car et al., 2008, 20)

To discuss the role of RCTs in establishing the effectiveness of medical apps, it is useful to consider an example. The developers of iResus, a smartphone app based on the UK Resuscitation Council’s resuscitation guidelines algorithms, conducted an RCT to assess the impact of their app (Low et al., 2011). 31 junior doctors with life support training were randomly allocated into two groups. One group was provided with access to the iResus app and the control group was not provided with any cognitive aid. Performance was scored on the simulated cardiac arrest simulation test (CASTest).

The app arm performed significantly better in the test and the authors concluded that the app significantly improved performance. The authors justify the research design by arguing that “... most cardiac arrests do not occur near a wall poster, and most healthcare professionals do not carry card-based cognitive aids. Thus, we considered a study group using iResus compared with a control group with no cognitive aids to be most representative of the real world.” (Low et al., 2011, 260).

This reasoning can be criticised as, using the same logic, one could argue that most

clinicians will not have the iResus app installed on their phone. Furthermore, the app is very similar to the paper-based flowchart guidance issued by the Resuscitation Council, suggesting that this is an obvious control intervention. If the control group had access to the paper-based intervention (such as a printed flow chart of the bradycardia algorithm), the comparison arguably would have been more meaningful because it would have provided insight into how the type of medium impacts performance.

For example, a recent study have suggested that paper-based cognitive aid are favoured over the electronic version by trainee anaesthetists in a simulated pediatric cardiopulmonary resuscitation setting (Watkins et al., 2016). These criticisms of the iResus study highlights the difficulty of designing RCTs for medical apps.

Heathfield et al. (1998) identify key challenges for evaluating healthcare information technology interventions using RCTs; namely, RCTs are difficult to generalise and have low validity as they rarely establish the acceptability of interventions. They advocate the use of methods that combine qualitative and quantitative approaches.

Having discussed methodological and epistemological issues, offered examples from current evaluation studies and highlighted the general lack of independent and peer reviewed supporting evidence for medical apps, it is appropriate to consider potential risks associated with medical app use and how these could be mitigated.

### 2.4.2 Risks and unintended consequences

Although it is hard to find published examples of medical apps that have caused direct harm, the use of untested, incorrect or misleading apps can conceivably pose risks. Charles Perrow, a prominent scholar in human factors, argues that unintended consequences and accidents involving complex and tightly coupled technological systems are inevitable (Perrow, 1999).

Many healthcare processes can be characterised as complex and tightly coupled as they involve many actors and specialist knowledges, are time critical with little built-in slack, and inadvertent errors at key stages can have serious consequences down the line. For example, in transfusion medicine the mislabelling of a blood sample (“wrong blood in tube”) is a serious mistake that can be potentially catastrophic for the patient. Preventing the consequence of this error requires vigilant staff who can detect the error in time and stop the transfusion (Bolton-Maggs et al., 2015b). This is particularly challenging in time critical situations and during periods of high workloads and staff shortages.

Hence, as the adoption and level of sophistication of medical apps increase, the likelihood of introducing unanticipated negative impacts also increase. The current lack of evidence of negative impacts could be due to under-reporting, publication bias and a shortage of evaluations. What is clear is that the impacts of healthcare information technologies are complex and cannot be assumed as “given”. For example, a study of

clinical decision support systems by [Campbell et al. \(2006\)](#) suggests that computerised decision aids have unintended consequences, such as increasing workload, introducing new kinds of errors and making healthcare practitioners excessively dependent on technology.

Some of these negative impacts derive from the limited capacity of humans to process information, and are applicable to the introduction of most information and communication technologies in the workplace ([Lawler et al., 2011](#)). For instance, mobile technologies, such as smartphones, are a potential source of distraction ([Gill et al., 2012](#)) and could reduce patient safety in certain situations, such as in the operating theater ([Jorm and O’Sullivan, 2012](#)).

The American Association of Nurse Anesthetists issued a statement on mobile phone use which flag up a range of potential problems related to mobile devices ([AANA, 2012](#)). These include reduced clinical vigilance, hygiene issues due to bacterial contamination of the phone (further explored in [Albrecht et al., 2013](#)), privacy concerns related to misuse of the phone’s camera, interference with medical equipment, lack of validation of the clinical content of apps and the evolving state of regulation. These issues raise questions about the roles and responsibilities of medical app developers and publishers, app stores, individual healthcare practitioners, professional institutions and government bodies in regulating and quality assuring medical apps.

### 2.4.3 Regulation and quality assurance

There is debate and uncertainty over the regulation of medical apps (Visvanathan et al., 2012; Kamerow, 2013; Haffey et al., 2013b; Cortez et al., 2014). Lewis and Wyatt (2014) propose a four-level framework for assessing the risks of medical apps, ranging from individual self-assessment, professional peer review and formal review by local health organisation through to central government regulation for those apps that pose the highest risks. How such a risk model could be applied in practice remains to be seen and I will therefore consider existing measures. I have termed these the “*market-based*”, the “*centralised regulation*” and the “*trusted intermediaries*” approaches.

The “*market-based*” approach is the modus operandi of app marketplaces where users purchase and download apps, such as Google Play or Apple’s Appstore. It is based on the principle that the market self-adjusts: given competition, unsatisfactory apps fail because consumers favour the better apps. This approach is somewhat analogous to evolution through natural selection. It assumes that consumers have the information, knowledge and skills to make good decisions, and the power and motivation to influence markets. While consumers have some influence, consumer power has become a cliché and is limited unless it is well-organised (Denegri-Knott et al., 2006).

As discussed previously, not all app developers reach out to their users and app stores offer little to encourage collaboration. Consumers can also be misled into purchasing and using low quality apps. For instance, the Federal Trade Commission (FTC),



the US consumer protection agency, have investigated apps with unsubstantiated or misleading health claims. The company behind the “UltimEyes” app was fined \$150,000 for claiming that it improved users’ vision (FTC, 2015a). Another company claimed their app cured acne with the light emitted from a mobile device display (FTC, 2011). The FTC have also taken down apps that claim to diagnose melanoma (FTC, 2015b).

Recognising the importance of intervening regulatory bodies, such as the FTC, the “*centralised regulation*” approach to improving medical apps builds on existing legal frameworks. This includes product safety and consumer protection, but also medical device regulation. Although the legal definition of a “medical device” differ depending on jurisdiction, simply put it refers to healthcare products, such as medical equipment or drugs, that are subject to strict quality control because they could endanger patient health if they operate incorrectly or are unreliable.

The regulation of medical devices in the UK falls under the authority of the Medicines and Healthcare products Regulatory Agency, which have issued guidance for medical apps that is harmonised with European legislation (MHRA, 2010, 2014). In the US, the Food and Drug Administration (FDA) updated its advice regarding the regulation of medical apps in September 2013, and again in February 2015 (FDA, 2015).

According to the FDA (2015, 8), only those medical apps that are deemed to meet the criteria for a medical device (e.g. intended “for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease”) and “whose functionality

could pose a risk to a patient's safety if the mobile app were to not function as intended" are actively regulated. The MHRA have also made it clear that they will only actively regulate a small proportion of available medical apps.

Consequently, there are relatively few public cases where apps for healthcare practitioners have been withdrawn. For example, a medical imaging app for reviewing MRI and CT imagery was taken off the Apple app store for two years while it was being cleared by the FDA (Dolan, 2010). The FDA also informed Biosense Technologies that their "uChek Urine analyzer" app requires clearance (FDA, 2014; Dolan, 2013) and it has since been unavailable on the iTunes app store. Furthermore, a rheumatology app aimed at clinicians was withdrawn by Pfizer due to software bugs that caused inflammatory diseases activity to be scored incorrectly (Jelle Visser and Bouman, 2012).

Kamerow (2013) argues current regulatory policies reflect the huge effort required to regulate a changing sector. In the updated regulatory policies, a large portion of clinical apps are classed as "low-risk" and therefore outside the oversight priorities of regulators. Thus, the vast majority of medical apps fall outside the remit of regulators and require a different quality review mechanism. One alternative is the "*trusted intermediaries*" approach, where medical apps are "vetted" by a trusted third party.

There are several examples of such initiatives, including some medical libraries, the NHS Health Apps Library, iMedicalApps, Happtique and other websites. NHS England launched the Health Apps Library (HAL) website in March 2013, listing apps that are

“safe and trusted” for patient use (NHS Choices, 2013). HAL claim it will not approve apps that are likely to cause harm to patients. It is unclear how this is determined, although HAL apply the Information Standard branding to certain apps.

This is a certification scheme for health and social care information commissioned in 2009 also by NHS England. The certification is intended to show that healthcare information is clear, accurate, impartial, evidence-based and up-to-date (NHS England, 2013). To achieve certified status, products require adequately documented information writing processes, use of referencing, user testing and commitment to review material at least every three years (NHS England, 2013).

Predating HAL, the iMedicalApps website have published reviews of medical apps since 2009 (iMedicalapps, 2013). Unlike HAL, it focuses on apps intended for healthcare professionals rather than patients. The website appears to be updated more frequently and offers more details of the strengths and weaknesses of the reviewed apps compared to HAL. However, it is difficult to know how they decide which apps to review and whether the reviewer possesses sufficient expertise in the area. iMedicalApps supports free text search and there are several reviews of apps related to blood transfusion and haematology at the time of writing (August 2016). The website is US-based and its reviews are therefore not always applicable to medical practice in the UK.

Intermediaries have met with limited long-term success as conducting in-depth reviews of medical apps is difficult and resource-intensive, and the business model

is unclear. [Huckvale et al. \(2015\)](#) showed that nearly 80% of the HAL-approved apps suffered from significant privacy limitations. For example, the apps sent information to third parties and did not store data using encryption. Since October 2015, the HAL website is no longer operational. Another notable certification programme, Happtique, was similarly deficient and even more short-lived:

“Happtique recently announced the suspension of their App Certification Program after [...] security flaws in apps [...] from Happtique’s first round of ‘certified’ apps. [...] these findings were an embarrassing setback for a program [...] intended to help patients and clinicians feel confident about their app selections. [...] Happtique took a year and a half to certify 16 apps from 10 developers. Similarly, the NHS Health Apps Library, which evaluates apps to ensure they are clinically safe, launched in March 2013 with about 70 apps; nearly a year later, its at about 100 apps. But these certified apps are a drop in the bucket compared to the nearly 50,000 apps in the iOS App Store Health/Fitness and Medical sections alone. These kinds of intensive programs are simply not scalable. And in a pay-for-certification model, it’s not necessarily the best that become certified but rather those with sufficiently deep pockets.” (para. 1, 7 [Misra, 2014](#))

## 2.5 Chapter summary

The purpose of this chapter was to situate the thesis in the existing research landscape and to identify key issues pertaining to the use, design and evaluation of medical apps for healthcare practitioners. It proved challenging to gain a complete overview of the state of research for several reasons. The literature is fragmented, there is a shortage of comprehensive systematic reviews and seminal work in eHealth predates current mobile technologies that have expanded rapidly in the last few years. Nonetheless, a number of conclusions can be drawn from this review.

Recent innovation and uptake of mobile apps have been fueled by gains in device manufacturing, faster network infrastructures and new commercial services that make it easy to publish software to billions of devices, as well as shifts in social and cultural norms and values. Earlier work in eHealth and social studies of technology provide a nuanced view of these developments.

Unlike hyped-up and technologically determinist accounts of how medical apps is “impacting on” healthcare in simple ways, the use, design and evaluation of medical apps can be understood as fluid socio-technical phenomena that are embedded in complex and politically-textured change processes taking place in the healthcare sector.

What sets medical apps apart from earlier generations of centrally imposed technology initiatives, such as the NHS National Programme for IT, is that apps can be adopted on an individual and “pick and mix” basis. This offers great flexibility to users, but makes it difficult to control access centrally. For the same reason, it is also difficult to study and draw conclusions about the impacts of app use in healthcare settings. Surveys offer some insight into the clinical use of medical apps, although it should be noted that findings may be biased towards adopters due to the widespread use of participant self-selection.

Numerous studies suggest that smartphone adoption is approaching a saturation point among some categories of healthcare practitioners. For example, the smartphone is a highly valued tool among junior doctors as it can support work tasks and increase

confidence when carrying out duties. Furthermore, both national evidence-based medical guidelines and local hospital guidelines are available in app form. Many of these initiatives have not yet been carefully evaluated (and possibly never will be), but there is some evidence that apps could promote the use of medical guidelines and improve clinical decision making. For example, the IAPP improved the dissemination of antibiotics prescription policies among junior doctors.

The use of apps in medical education is well under way. The mobile learning approach is advocated by some scholars as it could extend earlier e-learning initiatives by offering “just in time” and situated learning experiences in and beyond the classroom. Although textbooks and other learning resources are available as apps, institutional support for using apps as part of medical education vary. Utilisation is low in some areas of medical practice and technical problems have hampered initiatives in the past.

Furthermore, apps spanning a wide range of specialties have been found to suffer from important shortcomings, and there is quite vocal concern among some scholars and commentators that their use could be detrimental to patient safety. Others, such as the American Association of Nurse Anesthetists, have warned that the clinical use of mobile devices in general could have serious side effects, such as reducing clinical vigilance by creating distractions, causing an over-reliance on technology, jeopardising patient confidentiality and contributing to spreading bacterial infections.

Mitigating these risks is not trivial and requires multiple interventions. Attempts

at top-down regulation of medical apps have met with limited success as the majority of medical apps fall outside the remit of regulators. Indeed, some of the most publicised examples of apps that have been withdrawn from the market originate from consumer protection agencies targeting consumer-oriented apps which make misleading marketing claims, rather than from the bodies that regulate medical device safety.

Repeated calls from scholars and medical professionals for a “certified selection” or “white-list” of trusted medical apps also look increasingly unlikely to gain traction. Notable initiatives, such as the defunct NHS “Health Apps Library” and Happtique, which both intended to offer comprehensive app certification programmes, have failed to review apps in a transparent, effective and timely fashion.

A more promising approach is to invest in training to enable healthcare practitioner to manage the opportunities and perils of (untested) medical apps. The notion of an “eHealth literacy” (or “medical app literacy”) is pertinent as practitioners retain responsibility to patients and must exercise caution whether they rely on a paper-based medical guideline or an “appified” version. Although some medical schools have encouraged their students to learn about and create apps, other educational programmes may be failing to provide students with the necessary IT skills and knowledge.

A novel way to attempt to tackle this issue is to develop mechanisms that encourage healthcare practitioners to participate actively in the design and evaluation of medical apps. Failure to involve healthcare practitioners in the development process, together

with a general lack of medical app evaluation research, are among the most frequently cited causes of deficiencies in apps. Thus, there is a need for collaborative app design and evaluation research across professional boundaries.

The open source and open science movements could offer lessons for such an endeavor. These seek to promote increased transparency and openness in software development and medical research by opening up access to computer code and research data, including data from clinical trials. These approaches could potentially make it easier to inspect how apps work, and to assess their correctness. However, there are as yet few examples where this strategy has been successfully used. Apart from a small number of counter-examples, political and cultural barriers, such as entrenched power structures, have previously impeded these approaches in medicine.

Additionally, it is critical to develop a more integrated approach to app development that incorporates iterative design with evaluation research. Perspectives from user-centered design, co-design, user innovation and evaluation research are valuable in furthering this agenda. As are insights from the social studies of technology and innovation that suggest that design, implementation and innovation should be understood as interleaving processes. Thus, simple linear models of the software life-cycle are misleading and brush over the potential for innovations by users. Additionally, there is a need to develop appropriate app evaluation methods that strike a balance between validity, reliability, cost and rigour, and which generates data that can be



used to improve the quality and credibility of apps.

To summarise, the growing adoption of apps by practitioners raise questions about the extent to which medical apps are safe to use and how one would determine this. It also raises questions about how development and evaluation processes should be carried out to ensure medical apps are “fit for purpose”. There is little research evidence to answer these questions with confidence. Indeed, the impacts of medical app use on clinical outcomes is rarely known and few studies have demonstrated the mechanisms by which apps may have contributed to improvements in actual patient outcomes. Until stronger evidence is available, the use of medical apps will remain contentious.

## **Chapter 3:**

# **Blood transfusion in the UK**

This chapter aims to provide a concise introduction to blood transfusion in a UK context. Knowledge of the composition, manufacture and clinical use of blood components underpin the assumptions, rationale and research strategy of the thesis. In this chapter, I discuss these topics with particular emphasis on the correct care of patients who require irradiated and Cytomegalovirus (CMV) negative blood components. The last part of the chapter draws on learning materials that I developed for the Special Blood Components app, and which has been reviewed by the research collaborators acknowledged in the preface of the thesis. The chapter concludes with a summary of the main findings.

### 3.1 Composition and function of human blood

Blood is a tissue that interacts with many systems within the body, such as the circulatory, immune and respiratory systems. It is vital for the transportation of nutrients, gaseous exchange, defending against infections, healing wounds and regulating temperature (Schaller et al., 2008, 8). Moreover, blood is separable into four main components. *Plasma* makes up about 55% of human blood by volume and is composed mostly of water, together with small amounts of mineral salts, ions, carbohydrates, amino acids, gases and products of metabolism (Schaller et al., 2008, 12). Suspended in the plasma are three types of blood cells (figure 3.1).

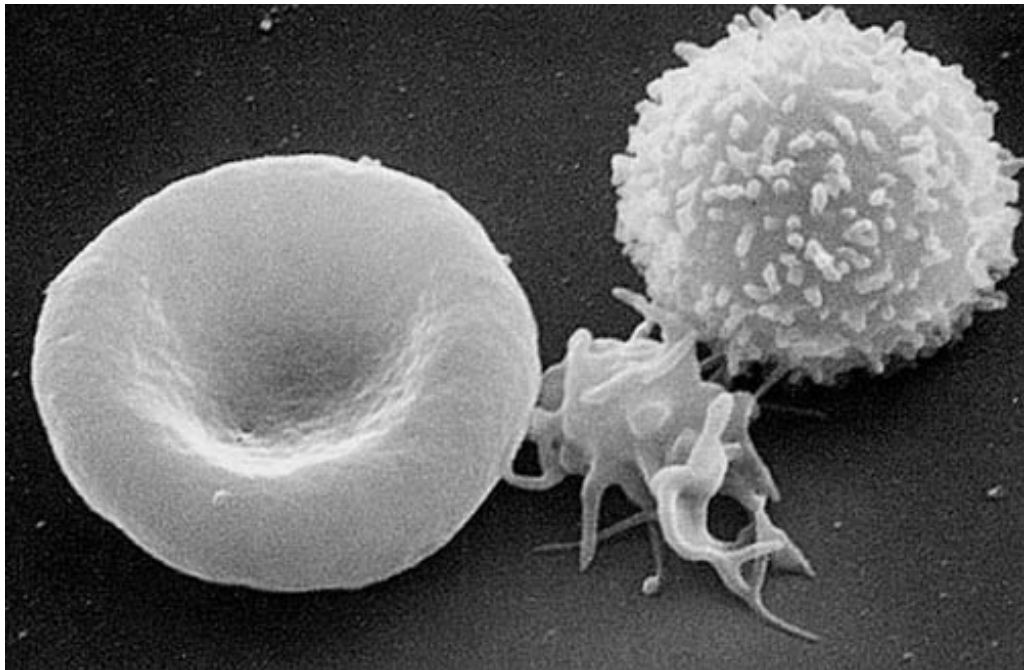


Figure 3.1: Scanning electron microscope (SEM) image of a red blood cell, an activated platelet cell and a white blood cell (t-lymphocyte). Public domain image by [National Cancer Institute](#) (2011).

*Red blood cells* (erythrocytes) account for about 45% of human blood by volume. They contain haemoglobin, a protein that binds oxygen required for cell metabolism (Schaller et al., 2008, 8). Red blood cells are essential for the oxygenation of the body's tissues and for removing carbon dioxide produced by cellular respiration. *Platelet cells* (thrombocytes), together with fibrinogen and other proteins (clotting factors), are involved in the formation of blood clots that stop bleeding. *White blood cells* (leucocytes) is an umbrella term for granulocytes, monocytes, macrophages, lymphocytes, and several subclasses of immune cells. They are an essential part of the immune system which prevents disease by identifying and destroying pathogens (Schaller et al., 2008, 10-11).

## 3.2 Blood component manufacture

Rather than transfusing whole blood, a single blood component, such as “packed red blood cells”, is normally used in the UK. This allows for more efficient use and storage of donated blood (Norfolk, 2013, 18). Thus, the production of high quality blood components is essential to offer safe, effective and sustainable healthcare services that fulfill legal requirements and public scrutiny (McClelland et al., 2010, 4). To meet the demand for blood, many countries have developed national systems for its collection, processing, storage, use and traceability. The “Guidelines for the Blood Transfusion Services in the UK” (known as the Red Book) provides a good overview of the system in place in the UK (JPAC, 2013).

UK blood donors are recruited on a voluntary basis. To prevent introducing unsafe blood into the national supply, donors are carefully screened and tested for blood-borne diseases (see ch.3 JPAC, 2013). Once approved, whole blood is collected through venesection or a specific blood component, such as red blood cells, is collected from the donor's bloodstream through apheresis whereby it is isolated by density using centrifugation and the other blood components are returned to the donor's circulation.

After collection, the blood components are processed to reduce the risk of transfusion complications (see ch.6 JPAC, 2013). A key stage is the removal of white blood cells from red blood cell, platelet and plasma components through filtration, a process known as leucodepletion (also termed leukoreduction). It was introduced 1999 in the UK to prevent transmission of variant Creutzfeldt-Jacob Disease (vCJD) (SaBTO, 2012a, 2). Since then all cellular blood components produced in the UK are routinely leucodepleted with the exception of granulocytes components (white blood cells) (Massey et al., 2014).

The effectiveness of the process is verified using statistical control. 90% of leucodepleted components in the UK have a white blood cell count of less than one million per unit with 95% statistical confidence (SaBTO, 2012b, 9). Failure rates vary between the national blood services and depending on the type of component. For example, in 703 tested units of pooled platelets produced by the SNBTS in October-December 2010, seven units exceeded five million white blood cells per unit (SaBTO, 2012b, 10).

Although, the effectiveness of the process cannot be 100% guaranteed as not every bag is tested, leucodepletion has proved effective in reducing the risk of several transfusion complications, including febrile transfusion reactions (Bassuni et al., 2008), cytomegalovirus (CMV) infection (SaBTO, 2012a) and Transfusion-Associated Graft versus Host Disease (TA-GvHD) (Bolton-Maggs et al., 2015a, 24). It has also reduced platelet transfusion failures (platelet refractoriness) (Murphy, 2015).

Blood components intended for patients at-risk of transfusion complications are further processed. For example, cellular blood components intended for patients at risk of TA-GvHD are exposed to a dose of 25-50 Gy (gray) of Gamma or X-ray irradiation (Treleaven et al., 2010, 41). Blood for fetuses, neonates and infants is separated into smaller “paedipacks” which contain irradiated blood from a single CMV-negative donor. Advances in chemical and photochemical treatment, known as pathogen inactivation, could further improve the safety of blood components (Prowse, 2013).

After processing, the blood components are packaged, labelled and stored in a controlled environment in blood establishments until they are released to stock and distributed to hospital blood banks for use. Individual blood bags (referred to as “units”) are bar-coded and tracked throughout their life-cycle in an information system. The system keeps a record of individual units of blood, associated donors and recipients. It enables units to be traced and recalled if a problem is discovered (a process known as ‘look-back’) (see ch.10 JPAC, 2013).

### 3.3 Clinical transfusion process

This section outlines the main steps of the clinical transfusion process, following the stages set out in figure 3.2. The process begins with a doctor or another healthcare practitioner who prescribes blood, such as a nurse authoriser (Pirie and Green, 2010), determining in consultation with the patient if the benefits of transfusion outweigh the risks (step 1). For example, patients who are ill as a result of a chronic, congenital (inherited) or acquired medical conditions, or who have lost blood in an accident or after an operation, may require one or more blood transfusions to recover. However, restrictive use of blood components is critical for preventing inappropriate transfusions and achieving a high level of safety (Hofman et al., 2011).

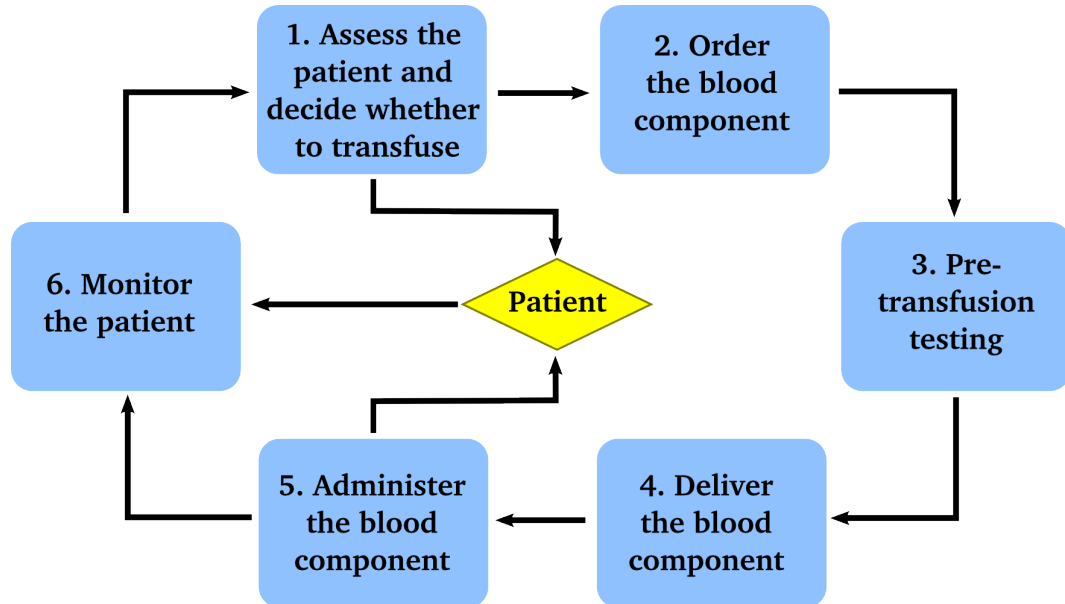


Figure 3.2: Visual representation of the six stages in the clinical transfusion process, adapted from McClelland et al. (2010, 4).

If a blood transfusion is prescribed, a request form stating the reason for the transfusion, the number and type of blood components required, and other details, such as any special transfusion requirements, is completed (step 2). A sample of the patient's blood, usually drawn by a nurse or phlebotomist, is sent together with the request form to the blood bank to ensure that compatible blood is issued. Laboratory staff analyse the blood sample to determine the patient's ABO blood group and other key information (step 3). This includes the presence of Rhesus D (RhD) antibodies, which is particularly important for preventing haemolytic disease of the newborn (HDN) (Urbaniaik and Griess, 2000).

Prior to the discovery of major blood groups, incompatible blood matching limited the safety and usefulness of transfusions. The development of the ABO system in 1901 by Karl Landsteiner led to an increase in the use of transfusions, especially during the first World War (Watkins, 2001, 243). Although the genetics and biochemistry of blood groups remain active research areas (Watkins, 2001, pp. 258-259), the ABO and subsequent Rhesus blood grouping systems enable compatible donors to be identified (table 3.1). The suffix minus sign indicates that no antibodies for the Rhesus D (RhD) antigen are present (i.e. the screen for RhD is negative). Antigens are proteins and carbohydrate structures on the surface of cells that the immune system uses to distinguish between the body's own cells and foreign cells. They determine whether a tissue, such as blood, will be rejected or not by the recipient (i.e. histocompatibility).



When incompatible cells are transfused into a patient they trigger the production of antibodies and an immune response that destroy (haemolyse) the cells. The severity of such a *haemolytic transfusion reaction* (HTR) vary from initially relatively mild symptoms (chills, dread, increased pulse and temperature) through to disseminated intravascular coagulation (DIC), multiple organ failure and death, unless the transfusion is stopped promptly (Strobel, 2008).

Compatibility testing is the laboratory process of determining that a blood component can be safely transfused into a patient<sup>1</sup>. In addition to blood group typing, compatibility testing includes antibody screening and cross-matching (American Association for Clinical Chemistry, 2015, para. 6).

<sup>1</sup>Interested readers should consult textbooks on the subject as only a brief overview of the laboratory processes can be offered here.

Table 3.1: The ABO and RhD blood groups, adapted from (Norfolk, 2013, 8-10).

Blood group	Antigens on red blood cells	Antibodies present in the blood plasma	Compatible donors
O-	None	anti-A, anti-B and anti-D*	O-
O+	RhD	anti-A and anti-B	O- or O+
A-	A	anti-B and anti-D*	O- or A-
A+	A and RhD	anti-B	O-, O+, A- or A+
B-	B	anti-A and anti-D*	O- or B-
B+	B and RhD	anti-A	O-, O+, B- or B+
AB-	A and B	anti-D*	O-, A-, B- or AB-
AB+	A, B and RhD	none	Donors of any group

\* Antibodies to RhD (anti-D) are only present in RhD negative patients sensitised to RhD positive blood, such as via transfusion or pregnancy (Norfolk, 2013, 9).

Thus, a “group and screen” is the ABO and RhD typing of the patient’s blood and the screening of it against other significant antibodies that could cause a haemolytic reaction (McClelland, 2007, 17; Norfolk, 2013, pp. 10-11). Furthermore, prior to the issue of a blood component, a serological or computerised cross-match is conducted (Norfolk, 2013; Chapman et al., 2000, 10). In the former, a sample of the patient’s plasma and the blood component is tested. Observing agglutination – the formation of one or more solid masses of clumped together red cells – in the test tube indicates a haemolytic reaction due to incompatible blood groups.

In the computerised cross-match (also referred to as electronic issue), compatible blood can quickly be issued without further serological testing based on information held in the patients electronic record, provided that (McClelland, 2007, 17):

- there are multiple robust records of the patient’s blood group type;
- the patient’s antibody screen is negative and;
- the patient’s identity, transfusion and testing history is reliably established.

Finally, to ensure that the correct unit is issued, blood bank staff also checks for any special requirements (discussed below). Once issued, the unit of blood is delivered to the patient’s ward by a porter where it is typically collected by a nurse (step 4). The nurse will check the blood bag (label details and signs of contamination) and match it against the patient’s identity and the prescription, and record the patient’s vital signs

(Gray and Illingworth, 2013, 8) before administering the unit of blood (step 5). This is a critical step as an undetected mistake up to this point can lead to an incompatible transfusion.

During the transfusion, the patient should be monitored (step 6) so that if there are signs of a transfusion reaction, the transfusion can be stopped promptly (Gray and Illingworth, 2013, 8). When an uneventful transfusion is finished, a nurse completes a form recording the blood bag identifier, date and patient. This information is stored for traceability purposes to aid investigations in the event of an incident. Incidents and near-misses are reported to UK haemovigilance schemes.

### 3.4 Safety and haemovigilance

The scientific understanding of human blood and safe blood transfusion practice has evolved considerably in the last century (Bain, 2005; Alter and Klein, 2008; Schneider and Drucker, 2006; Watkins, 2001). In the last decades, not least following the HIV/AIDS and Hepatitis C crises of the 1970s and early 1980s, major improvements have been implemented, such as better donor screening and recruitment, as well as more effective diagnostic tools and treatments to manage complications.

Prior to these advances, it is estimated that thousands of patients in Scotland alone contracted Hepatitis C or HIV/AIDS via unsafe blood transfusions (Penrose, 2015). The collection of blood from prison inmates, who had a higher incidence of Hepatitis C and

HIV/AIDS as a result of intravenous drug use and the sharing of needles, introduced tainted blood into the national supply. At the time, these conditions were not well understood, and diagnostic tests and treatments were unavailable (ibid).

A recent example highlighting similar issues is the Zika virus outbreaks. The virus spreads via the *Aedes* family of mosquito and can cause microcephaly in fetuses born to infected mothers (Mlakar et al., 2015). It has also recently been associated with other serious complications, such as Guillain-Barré Syndrome (Cao-Lormeau et al., 2016) (a neurological condition causing muscle weakness). The virus has been detected in asymptomatic blood donors in the South Pacific, raising concerns of transfusion-transmitted Zika infection via contaminated blood donations (Musso et al., 2014).

These examples vividly illustrate some of the challenge of ensuring, monitoring and improving the safety of blood transfusions. Making sure that the nearly three million annual transfusions in the UK (Bolton-Maggs and Cohen, 2013b) are as safe as possible is an ongoing effort that require that patients, doctors, nurses, blood bank staff and other professionals work together.

The professionally-led haemovigilance scheme Serious Hazards of Transfusion (SHOT) was founded in 1996 to facilitate this work in the UK (Williamson et al., 1998). SHOT collects and analyses “... anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom [...] recommendations are

put into its annual report which is then circulated to all the relevant organisations...” (SHOT, 2017, para. 1). SHOT owns the copyright to the data, which is not available in raw format or permitted to be reproduced without the organisation’s prior consent (Bolton-Maggs et al., 2016, 3).

Since monitoring began, SHOT have found that many of the current transfusion risks originate from limitations in workplace processes and practices, slips, mistakes and lapses in knowledge of healthcare staff (Bolton-Maggs et al., 2016, 22). For example, in 2014, Bolton-Maggs et al. (2015a, 31) attributed 750 out of 764 (98%) serious adverse events (SAE) to human error at any stage of the transfusion process. An SAE is defined as an:

“untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.” (Bolton-Maggs et al., 2015a, 31)

The reason why so many SAEs are attributed to human factor errors is that the manufacture, storage, distribution and clinical use of blood depends on a complex socio-technical system which involves many actors with specialised roles and knowledges. Studies of such systems, including modern medicine (Carayon and Wood, 2010) and nuclear power (Perrow, 1999), show that they are vulnerable because they are tightly coupled and have many points of failure which are difficult to predict, detect, prevent and recover from.

Table 3.2: Steps, possible errors, consequences and causes in the first three stages of the clinical transfusion process, abridged from [McClelland et al. \(2010, pp. 5-7\)](#).

<b>Stage 1. Assess patient and decide whether to transfuse</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Assess the clinical condition.	Unnecessary transfusion.	Transfusion associated circulatory overload (TACO).	Inadequate clinical assessment.
Decide on blood components and number of units.	Necessary transfusion not given.	Exposure to infection or immunological risk.	Lack of transfusion knowledge.
Obtain patient consent and record the decision.	Wrong component or dose given.	Risk of myocardial ischemia.	Unaware of importance of consent.
	Consent and decision not recorded.		Failure to follow guidelines.
<b>Stage 2. Order the blood component</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Identify patient.	Pre-transfusion sample taken from wrong patient.	Patient given wrong component or quantity.	Request form completed incorrectly.
Complete the blood request form or electronic order.	Failure to communicate transfusion requirements.	Fatal ABO incompatibility reaction.	Incorrect details on sample tube.
Pre-transfusion sampling.	Incorrect blood group in patient's record.	Young female sensitised to RhD.	Sample tube wrongly labelled.
Send blood sample and request to hospital blood bank.		Patient put at risk of TA-GvHD.	Wrong blood in tube (WBIT).
<b>Stage 3. Pre-transfusion testing</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Check sample and request form.	Wrong priority.	Delayed transfusion and risk of exsanguination.	Communication failures.
Prioritise according to urgency.	Failure to notice request error.	Incompatible transfusion due to mistaken patient identify.	Poor training.
Record any special requirements.	Special requirements not noted.	RhD sensitisation.	Failure by requesting clinical staff.
Determine and verify blood type against records.	Blood bank records not checked.	Haemolytic reaction due to missed alloantibody.	Inadequate or lost patient records.
Select units and test compatibility.	Incorrect lab tests.	Risk of TA-GvHD.	Defective reagents or equipment.
Label, record and dispatch units.	Failure to select appropriate units.		Suitable units not available.
	Dispatch to wrong destination.		

Table 3.3: Steps, possible errors, consequences and causes in the last three stages of the clinical transfusion process, abridged from [McClelland et al. \(2010, pp. 5-7\)](#).

<b>Stage 4. Deliver the blood component</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Pick up component from storage.	Wrong unit picked.	Fatal or serious haemolytic transfusion reaction due to wrong, damaged or expired unit.	Written patient details not used to select unit in storage.
Deliver promptly to clinical area.	Patients receive wrong component.	Unit wasted due to incorrect storage.	Unit delivered to wrong location.
Receive unit in clinical area.	Blood delivered to incorrect location.	Uncorrected severe anaemia.	Clinic staff unaware of delivery.
Store unit correctly until transfused.	Delay in supply.		Incorrect storage.
	Wrong storage e.g. placed in freezer.		
<b>Stage 5. Administer the blood component</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Match patient ID and prescription with unit label.	The transfusion is delayed.	Transfusion-associated sepsis.	Pack not inspected.
Inspect unit, check expiry date and that it matches patient's ABO and RhD group.	Contaminated unit is not detected.	Morbidity or death due to contaminated or expired unit.	Check of patient and unit not performed.
Ensure IV line is in order, take base line observations and start transfusion at flow rate instructed.	Expired unit is transfused.	Death due to ABO incompatibility.	Changes in component unnoticed.
	Patient receives incorrect blood component.	Volume overload (TACO).	The expired pack is not identified.
	Component transfused too quickly.	Unit not traceable.	Instructions for infusion unclear or not followed.
	Transfusion details not documented.		Breach of the standard operating procedure.
<b>Stage 6. Monitor the patient</b>			
<b>Steps</b>	<b>Possible errors</b>	<b>Consequences</b>	<b>Causes</b>
Observe patient's condition and vital signs.	Adverse reaction not detected and managed correctly.	Major morbidity or death due to transfusion reaction.	Patient not monitored or reaction never recognised.
Recognise and act on adverse event.	Delay in obtaining medical assistance.	Delayed response to adverse event.	Help not called or fails to respond.
Record outcome of transfusion.	Delay in assessing continued transfusion requirement.	Incomplete investigation of event.	Adverse reaction not treated correctly.
Assess additional transfusion.		Missing records to handle complaints.	

Tables 3.2 and 3.3 provide an overview of the steps, errors, causes and adverse outcomes that may occur in the clinical transfusion process. There are many things that can go wrong and errors can propagate throughout the system. For example, a misidentified patient can lead to the wrong patient getting the wrong blood unless the error is detected. Given the tight coupling between the sampling, laboratory testing, blood issuing, collection and transfusion, and the high workload, staff shortages and challenging working environments, this system shares many characteristics with Perrow's analysis of industrial accidents.

Fortunately, as a result of SHOT's work and measures to improve safety, the risk associated with blood transfusions in the UK have decreased greatly in the last decades (Cohen and Bolton-Maggs, 2012). Monitoring statistics suggest blood transfusions in the UK today carry a very low probability of serious complications (Bolton-Maggs and Cohen, 2013b). Furthermore, cost-effectiveness considerations and better understanding of the adverse effects associated with the liberal use of blood has promoted more restrictive transfusion policies (Holst et al., 2015; NHSBT, 2014), thereby side-stepping the inherent risks of a blood transfusion.

However, an area where mistakes continue to be frequently reported – albeit fortunately very rarely leads to serious complications – is in the supply of irradiated and cytomegalovirus (CMV) negative blood components to vulnerable patients who have special transfusion requirements.



### 3.5 Use of special blood components

Failures to provide patients with irradiated and Cytomegalovirus (CMV) negative blood components according to guidelines are reported to SHOT at a steady rate of about one hundred incidents per year (see figure 1.1 in chapter one). These incidents put patients at risk of Transfusion-Associated Graft versus Host Disease (TA-GvHD) and Transfusion-Transmitted CMV infection (TT-CMV), but fortunately only very rarely have a clinical impact. Only 14 cases of TA-GvHD (all fatal) (Bolton-Maggs and Cohen, 2013a, 135) and one (unconfirmed) case of TT-CMV (Bolton-Maggs et al., 2015a, 125) have been reported in the UK since 1996.

TA-GvHD is a rare, almost universally fatal disease caused by the transfusion of cellular blood (red cells, platelets and granulocytes) components containing viable lymphocytes. The transfused donor lymphocytes engraft and attack the recipient, causing skin rash, diarrhoea, liver disease, bone marrow failure and death from infection often within two-three weeks of the transfusion (McClelland, 2007, 41). The risk of developing TA-GvHD depends on three factors (Treleaven et al., 2010, 37):

- The number and viability of lymphocytes transfused;
- The susceptibility of the recipient's immune system to their engraftment and;
- The degree of immunological (HLA) disparity between donor and recipient.

In most cases, the recipient's immune system is capable of detecting and destroying the donor lymphocytes before they engraft. Immunodeficient patients (whether congenital or as a result of immunosuppressive treatment) are therefore at risk of TA-GvHD. However, TA-GvHD can also occur in immunocompetent recipients. If the donor and recipient share an HLA (Human Leucocyte Antigen) type, the recipient's immune system is unable to distinguish the donor lymphocytes from the body's own cells, allowing the donor lymphocytes to engraft. Shared HLA haplotypes are much more likely to occur in directed donations from relatives than between random donors and recipients. They are also present in HLA-matched transfusions.

As there is no effective treatment, current national guidelines require that all patients at risk of TA-GvHD receive cellular blood components that have been exposed to a dose of 25-50 Gy of Gamma or X-ray irradiation, thus inactivating the donor lymphocytes that give rise to the condition (Treleaven et al., 2010, 41). Additionally, all granulocyte transfusions must be irradiated as they contain a high concentration of lymphocytes, cannot be leucodepleted and are often given to immunodeficient patients (Massey et al., 2014, 7).

Cytomegalovirus (CMV), on the other hand, is common herpes virus that is harmless in healthy individuals, but can lead to lifelong disability or death in vulnerable patients, such as neonates (SaBTO, 2012b, 16). Providing patients at risk of CMV infection with blood components manufactured from donors who screen negative to

CMV can prevent transfusion-transmitted CMV (TT-CMV) infection [SaBTO \(2012a\)](#). In 2012 the indications for CMV-negative blood components were updated in light of evidence showing that the removal of leucocytes from red cells and platelets through leucodepletion significantly reduces the risk of TT-CMV ([SaBTO, 2012b,a](#)).

Furthermore, there is growing evidence to suggest that leucodepletion has reduced the incidence of TA-GvHD (for a recent discussion see [Hui et al. \(2015\)](#)). Despite almost a thousand failures to provide irradiated components according to guidelines, there have only been two cases of TA-GvHD in the UK in the decade after universal leucodepletion was introduced ([Treleaven et al., 2010](#), 41). However, just as there are patients for whom leucodepletion does not offer sufficient protection against CMV infection ([SaBTO, 2012b](#), 11), leucodepletion cannot be relied upon to prevent TA-GvHD:

“Leucodepletion [...] provides some degree of protection but must not be relied upon since not all units are tested to ensure adequate reduction in leucocytes and there are some failures. In addition, there is no scientific evidence that for the most immunosuppressed, LD is adequate, and indeed animal evidence that LD is not adequate. [...] therefore irradiation continues to be indicated for at-risk groups for the foreseeable [sic] future and it is important that clinicians work to ensure that this guidance is met.” ([Bolton-Maggs et al., 2015a](#), pp. 23-24)

Until new evidence or component manufacturing methods are available, the correct use of irradiated and CMV-negative blood components according to current guidelines is essential. Irradiated and/or CMV-negative components are indicated only to those at risk of TA-GvHD or TT-CMV. Such patients are a minority of transfusion recipients and fall under the umbrella term of patients with “special requirements”.

## 3.6 Causes of mistakes and mitigation strategies

There are multiple reasons why special requirements fail to be provided to at-risk patients including: incorrectly completed blood request forms (Taylor et al., 2008, 46), failures to check medical records (Bolton-Maggs and Cohen, 2012, 32), poor handover during shared patient care (Cohen et al., 2010, 41), inadequate bedside checks (Taylor et al., 2008, 31) and errors in the laboratory systems (Bolton-Maggs and Cohen, 2012, 56). Protecting patients with special requirements is another reason that it is vital that the right patient receives the right blood component (Gray and Illingworth, 2013).

Overcoming these issues requires multiple interventions. Root cause analysis indicates that inadequate practitioner knowledge is a recurring and preventable cause of mistakes (Bolton-Maggs and Cohen, 2012, 33). Practitioners involved in blood transfusion must be aware of the rationale and indications for irradiated and CMV-negative blood to be able to request it as appropriate. Furthermore, they must have sufficient knowledge to critically assess clinical decisions and spot potential mistakes elsewhere in the transfusion chain (depicted in figure 3.3). SHOT have also identified several additional measures for improving practice, including:

- ensuring blood components are ordered correctly and that systems for ordering facilitates this (Knowles and Cohen, 2011, 26).
- educating patients with special requirements, including providing them with a card that they can show to healthcare staff (Bolton-Maggs and Cohen, 2012, p.34).

- conducting thorough pre-transfusion bedside checks, ensuring such checks are uninterrupted (Knowles and Cohen, 2011, 61) and supported with a checklist (Bolton-Maggs and Cohen, 2013a, 62).
- the appropriate use of computerised alerts and flags (Bolton-Maggs and Cohen, 2012, 7), taking care to ensure that setting flags is carried out carefully and verified by multiple members of staff (Bolton-Maggs and Cohen, 2012, 51).

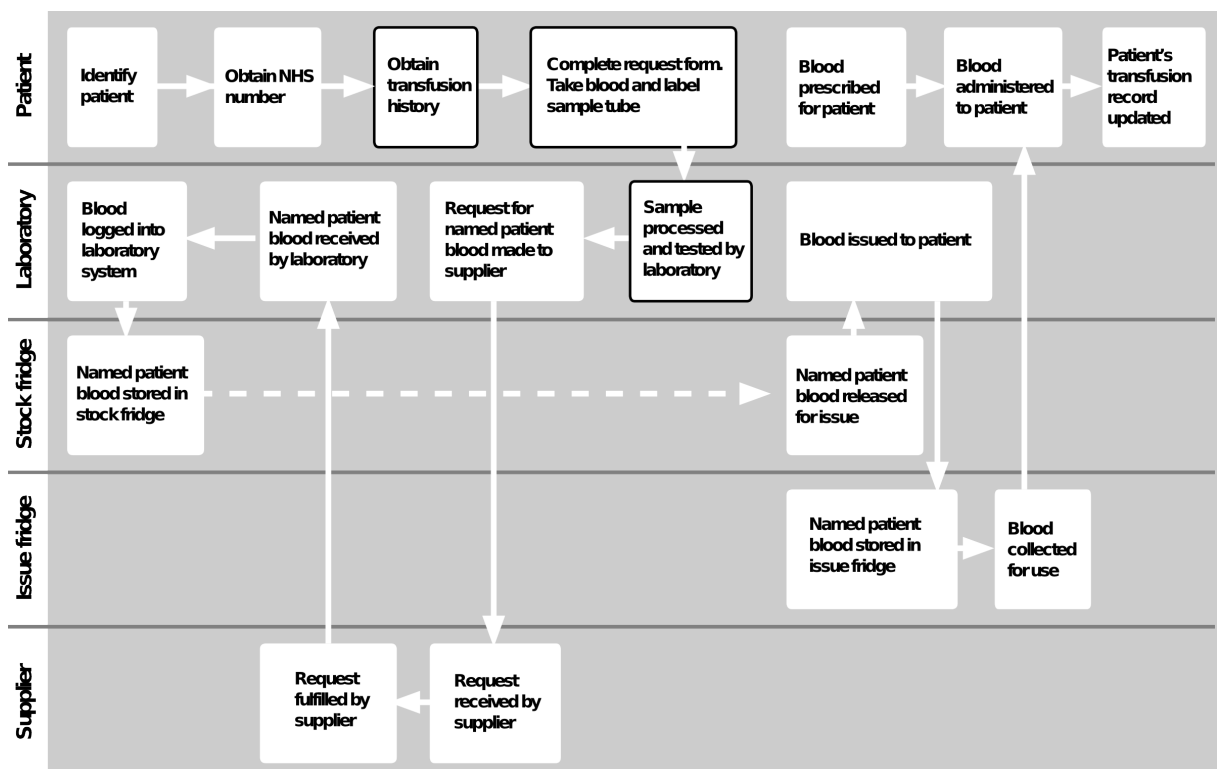


Figure 3.3: Process map for special requirements, adapted from National Patient Safety Agency (2006, 20). The three middle boxes marked with strong black borders indicate steps where the need for special requirements should be identified. Any units will additionally need to be verified at other points in the process, such as during pretransfusion checks, to ensure special requirements are met.

Furthermore, there are many interventions aiming to improve transfusion practice and knowledge, including: videos, such as 2002 production *The Strange Case of Penny Allison*, starring Hugh Laurie and Imelda Staunton; animated short films, such as a recent production highlighting critical stages in the transfusion process (figure 3.4); paper-based aids, such as pocket-sized cards (figure 3.5); and digital aids, such as the NHSBT Platelets App reviewed in chapter four (Estcourt et al., 2013).

However, as discussed in the introduction, despite recommendations by Knowles and Cohen (2011, 28) and Cohen et al. (2010, 55) to improve this area of blood transfusion education, there are few dedicated learning resources available to practitioners. In particular, the Learn Blood Transfusion e-learning program (figure 3.6), which forms a mandatory part of professional development of practitioners involved in blood transfusions in many parts of the UK, does not address special requirements in detail in the modules on safe transfusion practice.

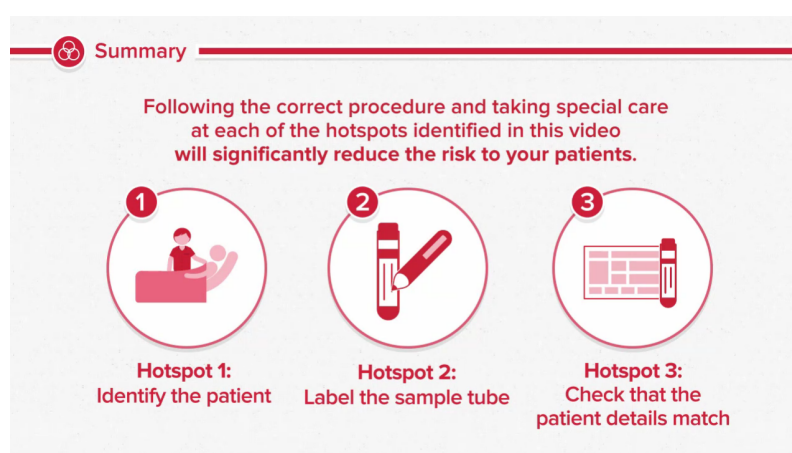


Figure 3.4: Screenshot from an animated film highlighting sources of error (“hotspots”) in the pre-transfusion sampling process. Courtesy of SNBTS.

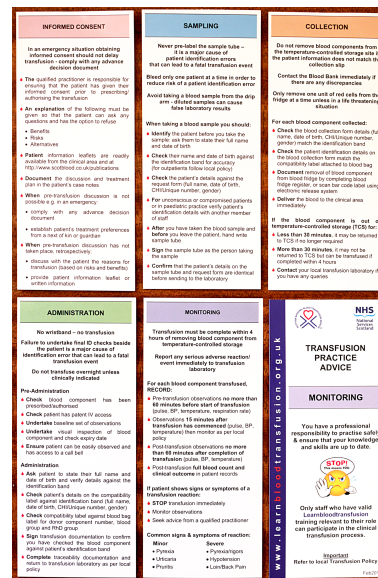


Figure 3.5: Cards summarizing the do's and don'ts at each step of the clinical transfusion process. Courtesy of SNBTS.

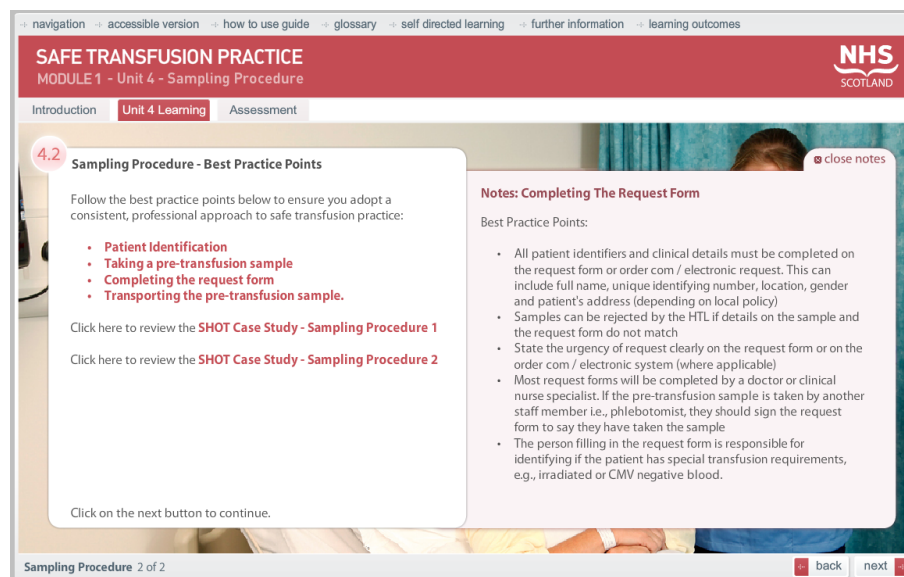


Figure 3.6: Screenshot from the Learn Blood Transfusion e-learning platform used by healthcare practitioners in the UK. Courtesy of SNBTS.

## 3.7 Chapter summary

The purpose of this chapter was to provide an overview of the manufacture and clinical use of blood components in the UK. The review demonstrated that current practices are the result of evolving scientific advances on multiple fronts. This include understanding of human blood (single component therapy, grouping and antibody testing), blood-borne diseases (HIV, Hepatitis C, Zika, etc), blood transfusion safety (e.g. donor screening, haemovigilance, patient blood management and management of transfusion reactions) and human factors (e.g. to mitigate errors in the workplace).

A pertinent issue that merits further research is the role (and cost-effectiveness) of component manufacturing processes, such as pathogen inactivation, in eliminating the need to separately manufacture special components for certain patient groups. However, until such developments, the correct use of irradiated and Cytomegalovirus (CMV) negative blood components remains critical to prevent two very rare and serious conditions in vulnerable patients: transfusion associated Graft versus Host Disease (TA-GvHD) and transfusion-transmitted Cytomegalovirus (TT-CMV) infection.

Preventing mistakes in the use of these components is difficult as there are multiple causes requiring targeted interventions. Many problems can be traced back to the working environment, such as understaffing. Inadequate knowledge in practitioners is a preventable cause of mistakes. Creating educational resources for the correct use of these components is necessary as there are few dedicated learning interventions.



In summary, this review of the composition, manufacture and use of blood components has provided a foundation for which to attempt to intervene in a complex medical system. It has informed subsequent stages of the research which seeks to improve the correct use of irradiated and CMV negative blood components by creating a mobile learning intervention for healthcare practitioners.

# **Chapter 4:**

## **Methodology**

This chapter provides an overview of the research methodology adopted in the thesis. It begins by discussing the main assumptions underpinning the research, and the aims, objectives and research questions. This is followed by a discussion of the methodological and theoretical framework, epistemological and ethical considerations, as well as software development process. Details of specific methods adopted in each of the five empirical studies are provided in their respective chapters.

## 4.1 Aims and assumptions

Many of the medical apps currently available to healthcare practitioners suffer from notable shortcomings due to weaknesses in the design and evaluation processes that gave rise to them. Effective interdisciplinary collaboration and mixed-methods evaluations have been identified by scholars in eHealth as critical to the success of healthcare information technology interventions. **Thus, the aim of the research was to explore how the quality and credibility of medical apps might be improved through collaborative design and evaluation processes.**

To investigate this question, I reflected on transferable lessons from the collaborative development and evaluation of a new mobile app in transfusion medicine. I adopted a working definition of “quality” that encompassed three main aspects: the *clarity, correctness and traceability of medical information* contained in an app (1); the *accuracy of calculations or recommendations* returned by an app, such as drug dosing (2); and the *ease of use, including the ability to avert, rather than induce, errors* (3).

Furthermore, I defined the “credibility” of a medical app as a *judgement of its trustworthiness based on published evidence*. “Weighing up the evidence” is a central part of such a judgement. However, as the absence of published evidence is the rule rather than the exception for many medical apps, other aspects will naturally influence judgement. For example, endorsement from institutions or peers could profoundly influence the decision to adopt or reject an app.

To limit the scope, I focused on the use, design and evaluation of medical apps intended to improve blood transfusion practice and education in a UK context. I set out specific research objectives (presented in chapter one, table 1.3), which included reviewing prior work, analysing and evaluating the Special Blood Components (SBC) mobile learning app at several stages, and creating tools and methods to support collaborative development and evaluation with healthcare professionals.

The research objectives were addressed in two literature reviews (reported in chapters two and three) and five empirical studies (presented in chapters five through nine). The empirical studies relied on a mix of qualitative and quantitative methods to answer specific research questions, which are summarised in table 4.1. As they are discussed in their respective chapters, I will not detail the methods adopted in each study here. Instead, I will now discuss and justify my research approach, including theoretical, methodological and ethical considerations.

## 4.2 Theoretical and methodological framework

Although there are many well-established software development methodologies, such as Soft Systems (Checkland, 2000), I have been unable to identify any which are directly applicable to the collaborative design and evaluation of medical apps. Furthermore, bridging differences in the priorities, methods and epistemologies of technical development, and the rigorous evaluation of healthcare information technology inter-

Table 4.1: Research questions by study number and chapter.

**Study 1 - Review of an Existing Transfusion App (Chapter 4):**

- 1a. What strengths and weaknesses do practitioners identify in an existing app aiming to improve a specific area of blood transfusion practice?*
- 1b. To what extent could their observations transfer to other medical apps?*

**Study 2 - Concept Validation of the Proposed App (Chapter 5):**

- 2a. What are different practitioners' experiences of "special blood components"?*
- 2b. What are their views on the causes of mistakes and effective interventions?*
- 2c. What strengths and weaknesses do they identify in the proposed app?*

**Study 3 - Collaborative App Design with the WAE (Chapter 6):**

- 3a. To what extent is the Web App Editor an effective and easy to use tool that enables novice app developers to acquire technical and collaborative skills?*

**Study 4 - Usability Evaluation of the SBC App (Chapter 7):**

- 4a. How do medical students rate the usability and content of the revised SBC app?*
- 4b. What further improvements to the app do they identify?*

**Study 5 - A Randomised Controlled Pilot of the SBC App (Chapter 8):**

- 5a. To what extent is the updated SBC app effective in improving the knowledge of special blood components in staff with recent transfusion training?*
- 5b. How do staff rate the app in terms of the ease of finding information, enjoyment of use, likelihood to use again and to recommend to others?*
- 5c. How does the efficacy and ratings of the app compare to existing local hospital guidelines?*

ventions is challenging and require interdisciplinary understanding (Pagliari, 2007). For this reason, it was necessary to assemble a heterogenous framework by identifying methodological and theoretical building blocks from several disciplines through a process of “bricolage” (Turkle and Papert, 1991, 168).

### 4.2.1 Action research

Foundational building blocks of the methodological framework originate from the action research tradition. This is an interventionist approach to conducting research that is concerned with creating, evaluating and refining solutions to practical problems through active involvement of stakeholders. It can be traced back to work in the 1940s by the social psychologist Kurt Lewin, here summarised by Adelman (1993, 9):

“Action research for Lewin was exemplified by the discussion of problems followed by group decisions on how to proceed. Action research must include the active participation by those who have to carry out the work in the exploration of problems that they identify and anticipate. [...] The group would decide on when a particular plan or strategy had been exhausted and fulfilled, come to nothing, and would bring to these discussions newly perceived problems.”

Although the validity of action research is contested by “positivists” for its interventionist and pluralistic underpinnings, it is an established methodology in fields such as nursing (Meyer, 1993, 2000), education (Carr and Kemmis, 2003), information systems development (Checkland and Poulter, 2010) and human computer interaction (Hayes, 2011). Because it is used in such a wide range of contexts and there are many

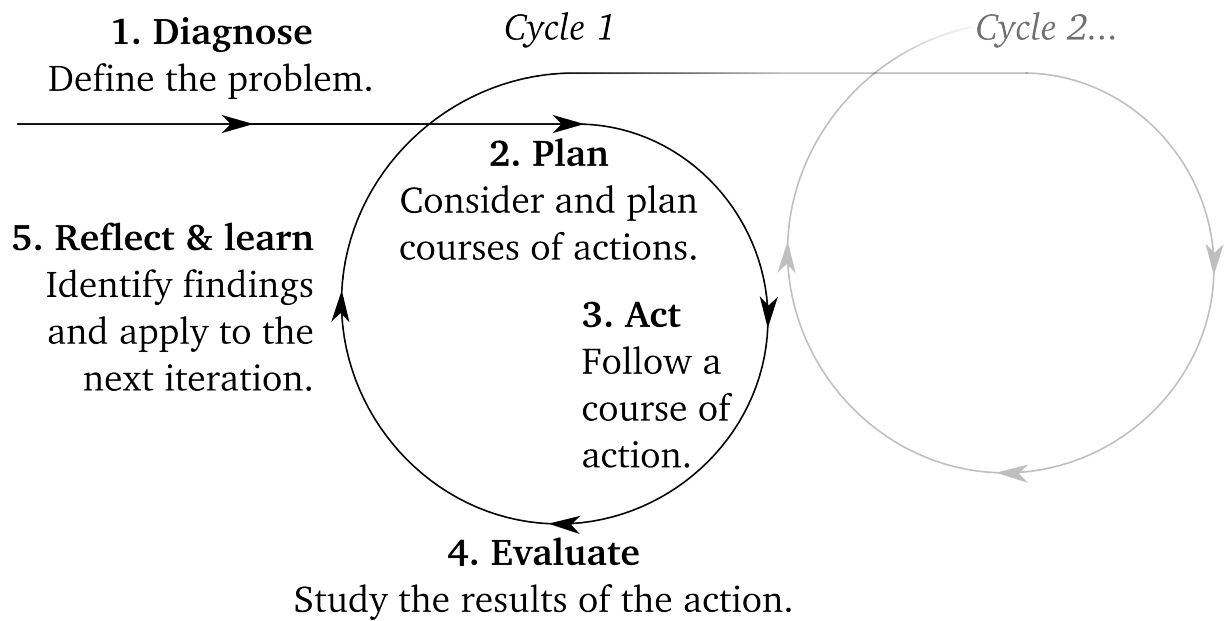


Figure 4.1: Visual representation of the iterative action research cycle, adapted after [Susman and Evered \(1978\)](#).

forms of action research, there is no single accepted definition ([Reason and Bradbury, 2006](#), 1). However, most definitions place emphasis on the following characteristics:

- A dual objective of intervening to initiate some “desirable” change, while simultaneously generating answers to research questions through the application of scientific methods;
- A participative approach to the research process, dependent on close collaboration with stakeholders; and
- Learning and theorisation through a repeating cycle of planning, acting, observing and reflecting (fig. 4.1).

Furthermore, [Greenhalgh et al. \(2004, 30-31\)](#) singles out action research as an appropriate method for healthcare innovation research as it “focuses on change and improvement; explicitly and pro-actively involves participants in the research process; is educational for all involved; looks at questions that arise from practice; involves a cyclical process of collecting, feeding back, and reflecting on data; and is a process that generates knowledge.”

Thus, the development and evaluation of the Special Blood Components app was structured so as to enable clinicians and other stakeholders to critique ideas and prototypes throughout in the design process. The decision to work closely with potential users in an iterative manner hint at two other important building blocks of the methodological framework, namely user-centered design and agile development.

#### **4.2.2 User-centered design and agile development**

The development work was organised into iterations involving planning, development, evaluation and re-development based on user feedback. The Special Blood Component (SBC) app went through three main iterations that were relatively short in duration to allow changes in user requirements and research direction, particularly at the start of the project. Towards the end of the project, the iterations were longer due to the increasing burden of conducting the research, including data collection and analysis of findings.



Organising the work in short iterations borrows from agile software development methodologies (Abrahamsson, 2002). Agile approaches promote early delivery of functioning, but incomplete software to users to allow unexpected changes to be identified early in the design process when the cost of making significant changes are still low. One of the unexpected changes in research direction – that only became clear after the second study – was the need for better app development tools to allow work in progress to be shared effectively with collaborators to ensure the final product was accurate, easy to use and met the needs of users.

Thus, significant effort went into creating a web-based collaborative app editor to support processes of learning about, modifying and creating mobile apps with others. This system, called the Web App Editor (WAE), became an important tool for creating the SBC app, and for exploring how collaborative development and evaluation could improve the quality and credibility of medical apps.

Inspired by concepts from user innovation (von Hippel, 1998, 2005), and calls to adopt open source principles to better organise the development of medical apps (van Velsen et al., 2013), this aspect of the research went beyond most user-centered design methodologies as creating tools for the collaborative development of apps could be said to amount to a “transformation” design approach:

“Transformation design acknowledges that ‘design is never done’ [...] the challenge is not how to design a response to a current issue, but how to design a means of continually responding, adapting and innovating. Transformation design seeks to leave behind not only the shape of a new solution, but the tools,

skills and organisational capacity for ongoing change. This builds on the reality that ‘everybody is a designer in everyday life’ (Burns et al., 2006, 21)

That is to say, the tool is general enough to not only help develop the SBC app, but has also been used in other projects (some of which are discussed in chapter seven).

### 4.3 Epistemological position

Like many studies involving the design and evaluation of computer software or health-care interventions, the research questions reflect a commitment to both “practical” and “theoretical” concerns (Hevner et al., 2004), which historically have not enjoyed equal status in academia (Simon, 1996, 112). The interventionist and practically-oriented nature of action research can raise concerns about validity, reliability and generalisability.

As a methodology, action research has been criticised for its lack of “objectivity” and rigor compared to positivist methodologies. However, these criticisms have been addressed by Susman and Evered (1978), Checkland and Holwell (1998), Meyer (2000) and others. Nevertheless, it is important to consider the epistemological position I adopted in this project. Epistemology is concerned with what counts as “knowledge”, and by which means or methods knowledge claims can be supported (or refuted).

Drawing on the tradition of Popper, Kuhn and feminist critiques of science and technology, this research subscribes to a post-positivist (i.e. interpretivist), social constructivist and pluralist epistemology (Miller, 1983; Racher and Robinson, 2002; Kuhn,

1970; Haraway, 1988). Critical research in the post-positivist tradition does not claim to be “objective” as it acknowledges the “situatedness” of the researcher (Haraway, 1988).

That is to say, researchers are not isolated from the social and cultural context they operate in (Bloor, 1991), and their work is also shaped by professional socialisation (Kuhn, 1970) and personal experiences (Haraway, 1988). Acknowledging these social dimensions of research as sources of potential bias, and adopting a reflexive approach (Finlay, 2002), contrasts approaches where the researcher is portrayed as an outside, invisible, objective and dispassionate observer waiting for the world to reveal its true nature.

Like most work in the social sciences, I reject the notion of a single discoverable “truth”. Instead, I prefer the notion that there are many possible narratives about the world (falsifiable conjectures in Popper’s terminology) that are socially constructed and mediated through personal, cultural, language and technological filters. Of course, operating in an interdisciplinary space, I must shift between epistemologies and play by the rules and conventions established in different research communities.

This position also embraces the pluralistic view that there are several way of knowing and inquiring into the world, each with strengths and weaknesses, and that multiple perspectives are important to understand real-world problems (Miller et al., 2008; Rittel and Webber, 1973). It is a worldview resonates with the socio-technical com-

plexity associated with the development, evaluation and implementation of healthcare information technologies, where mixed-methods research is common.

## **4.4 Ethical considerations**

All researchers must examine the ethical implications of their proposed research to ensure participants' interests are respected and no harm is caused. At the start of the project and prior to commencing study one, I completed the University of Edinburgh ethics self-audit procedure. The outcome of this process was that no significant ethical issues could be identified that could not be mitigated by standard good practices, such as the anonymisation of participants.

Participating in the studies was voluntary and deemed unlikely to cause stress, negative feelings or harm to participants. Participants were provided with accurate information about the purpose of the research and what they were being asked to do and asked for their consent to participate prior to taking part (see appendices for copies of the participant information and consent sheets). The main burden on participants was the time that it takes to complete the research tasks. I hence designed the tasks to be fast to complete by reducing the number of questions and streamlining the participation process. For example, the Web App Trial system went through several stages of prototyping and piloting with this aim. Moreover, participants were encouraged to take part at a time and in a location that was convenient to them.

Furthermore, as far as possible all results were reported in aggregate to ensure participants' anonymity. Names, contact details and any personal information relating to individual participants was not disclosed, unless express written permission was granted by the participant. When using quotes, statements were reported so as to preserve the respondent's anonymity.

At the time of the fourth study, I learned that research involving the National Health Service (including its staff) may require additional permissions, such as management approval. The first route I explored for obtaining NHS ethical review and clearance was through the Health Research Authority (HRA) research ethics committee (REC) system. The HRA provides an online self-assessment tool to determine if a research project requires ethics permission from a REC ([HRA](#), no year). Thus, on July 19 2013, I completed the HRA self-assessment tool. The result of the self-assessment was that the fourth study did not require review by a research ethics committee as it involved students. As the study targeted medical students and was conducted on university premises in close collaboration with university staff, written management clearance from the healthboard was not sought.

For study five, which involved NHS staff rather than medical students, I submitted an Integrated Research Application System (IRAS) application on August 19 2014. I then applied for permission from the relevant NHS healthboard to recruit NHS staff. The result of the IRAS application was that REC approval was not required as the

study did not recruit patients. However, management permission was required and I submitted a project registration on September 26 2014 to the chair of the local quality improvement team. Approval was granted in early November 2014 from the health-board Clinical Governance and Risk Management Support Team.

On reflection, the ethical governance of research involving NHS staff can be slow and difficult to navigate unless you have an existing affiliation with the NHS. It involved significant amount of waiting, extensive paperwork and communication with staff within the NHS. The advice I accessed was not always consistent and clear, and there appeared to be differences in procedures at the national, regional health board and local hospital level. Furthermore, the ethical assessment would likely have changed if the app could be classed as a Medical Device. It would have required approval by the Medicines and Healthcare Products Regulatory Agency. Similarly, if the research had involved patient data, it would have required full REC approval.

## 4.5 Software development process

The research and software development process is summarised in tables 4.2 and 4.3. Beyond this, I also developed a collaborative app editor and a system to conduct an online randomised controlled trial of the SBC app. The process, which began with paper mockups and prototypes, was more chaotic than these organised tables convey.

Table 4.2: Activities related to the development and evaluation of the Special Blood Components app, February to December 2013.

<b>Stage I - Ideas development (Feb-Apr 2013):</b>		
Idea generation	Feb 2013	When developing ideas Dr McClelland, medical advisor to the project, acted as a proxy user and domain expert. Our initial ideas changed over time as our understanding of the problem, stakeholders and contexts of use evolved. Analysis of SHOT data also informed this stage.
Paper mockups	Mar 2013	Where there were particular design challenges, resorting to pen and paper helped explore the choices quickly. For example, alternative page layouts and ways of organising content.
Functional prototypes	Apr 2013	The use of the jQuery Mobile framework allowed rapid construction of functional wireframes with graphical user interface elements. This enabled early testing and refinement of key interactions like navigation, search and filtering list items.
<b>Stage II - Concept validation and refinement (Apr-May 2013):</b>		
Consultation with clinicians	Apr 2013	To identify improvements and design lessons, clinicians were invited to review the usability and contents of several third party transfusion apps and our first prototype about special transfusion requirements (see studies 1 and 2 for details).
Prioritisation	May 2013	At this point, I had a long list of possible topics and urgently needed to decide on one. The comments from the clinicians, together with my own assessment of the feasibility and demand for different topics, led to the decision to pursue the topic of irradiated and CMV-negative blood components.
<b>stage III - Development, review and presentation (Jun-Oct 2013):</b>		
App development	Jun-Aug 2013	Completing a full version of the app required much work: programming new features, summarising medical articles and guidelines, refining data structures for the clinical indications, improving the visual design, enhancing usability, incorporating analytics, refactoring, testing and bug fixing the code, and performance and interoperability tweaks.
Informal review	Sep 2013	The app was then circulated for review to the clinicians who had been approached earlier and a few other critical friends. Most of them used the app's new feedback mechanism, which prompted them to submit feedback online, but in some cases feedback was captured via email or phone.
Presentation to BBTS	Oct 2013	After the review, I presented the app at the British Blood Transfusion Society's (BBTS) annual conference. Attendees were encouraged to try it out and comment through the evaluation system. This resulted in a few responses and a research opportunity to evaluate the SBC app with medical students.

Table 4.3: Activities related to the development and evaluation of the Special Blood Components app, January 2014 to September 2015.

<b>Stage IV - Usability evaluation and dissemination of results (Jan-Jul 2014):</b>		
Online usability evaluation	Jan 2014	The app was evaluated by 54 final year medical students during a compulsory training day (see study 3). No special approval was required since the ethical issues of involving students were covered by standard university procedures and the training organisers gave their permission. I was well-prepared since I had already developed and tested the app's feedback mechanism. These were fortunate circumstances as the timing coincided with my Major Progress Review (PhD milestone).
Analysis of evaluation results	Feb 2014	The analysis of the students' responses was straight-forward. Although most were unfamiliar with the topic, they identified several usability improvements and a need to expand the learning materials. This was addressed in the next version.
Presentation to SHOT	Jul 2014	I presented the findings from the student evaluation at the Serious Hazards of Transfusion (SHOT) annual symposium and received favourable feedback, suggesting the choice of topic resonated with the community.
<b>Stage V - Assessment of the impact of the app (Feb-Dec 2014):</b>		
Re-development	Feb-Nov 2014	I decided to rewrite the app from scratch because a new version of jQuery Mobile was released and I wanted to improve the code. Furthermore, I wanted to simplify the presentation of the indications and learning materials. Editing and quality-assuring the new learning materials was challenging and time-consuming, even with the help of several people (see acknowledgements).
NHS approval	May-Nov 2014	My collaborators and I had identified a need to assess the impact of the app in a more systematic way with a larger number clinicians. Thus, I began to construct patient scenarios to validate the app. To comply with the ethical and management rules governing research involving NHS staff, we prepared an extensive IRAS application. With the assistance of a respected senior clinician, the study was approved.
Randomised controlled pilot study	Nov-Dec 2014	Using a randomised pre-post study design, I evaluated the impact of the app on clinicians' knowledge about special blood components, comparing it to existing local hospital guidelines.
<b>Stage VI - Wrap-up and maintenance (Jan 2015-):</b>		
Thesis write up	Jan 2015-Nov 2016	The last part of the project have been dedicated to analysing the findings of the final study and writing up the PhD thesis and publications.
Promotion	Ongoing	I continue to work with collaborators to promote adoption of the app and maintain it.



### 4.5.1 Technical architecture, design decisions and stakeholders

There are many technical and design decisions that went into the making of the SBC app, and it is necessary to touch on some of these. Already at the start of the project I was faced with the important choice between a “native” or web-based architecture. The decision of native or web-based apps is contentious and the decision reflects individual developers’ taste and requirements (Huy and vanThanh, 2012).

HTML is the language of the Web and with the latest revision it has become more oriented towards the mobile domain. HTML5 includes application programming interfaces (APIs) for a range of previously unavailable functionality (Aghaee and Pautasso, 2010). For example, webcam and audio support, file handling, advanced graphics using WebGL and the canvas tag, access to embedded device sensors such as GPS, gyroscope and accelerometer, and real time peer-to-peer communication (webRTC). Some of the benefits of HTML5 over native apps are interoperability and greater familiarity for developers with prior experience of web design. The main drawbacks are slower performance and a more limited range of APIs compared to native platforms.

My methodology greatly influenced my decision. Developing web apps with the Web App Editor made it possible to quickly iterate designs and share them with collaborators in real-time. This would have been more difficult using native apps, as they would have to be compiled and published before testing (and for iOS devices this requires commercial server infrastructure that was unavailable to me).

Other reasons I chose to work with web technologies, over native programming languages, include that the hyper-text markup language (HTML), cascading style sheets (CSS) and Javascript are vendor neutral, open and viable technologies for creating apps (Korkmaz et al., 2011). For instance, in 2013 over half of more than 6000 surveyed app developers reported that they use HTML5 to create apps (Vision Mobile, 2013b, 3). Having briefly explored the key technological choices, I will now turn to some of the design challenges that I encountered and how I resolved them.

Safety, accuracy, speed and usability were some of the key considerations that shaped the design process. A considerable amount of time was allocated to ensuring that the content of the app accurately reflected the best available evidence-based guidelines. Similarly, it was important to ensure that the information was presented clearly so as to minimise the risk of misinterpretation and potentially inducing new forms of errors. For the same reason, ensuring a high level of usability was a key priority and resulted in evaluations of this aspect at several stages of the design process.

One of the most challenging design aspects was the level of complexity of the topic and the need to present information in a way that made it easy for a newcomer to gain an overview quickly, while also offering a comprehensive summary that allowed users to dive into details when necessary. For instance, I experimented with using graphical icons based on the traffic light system to indicate when irradiated or cytomegalovirus negative blood is required. Clicking on the icon would then expand a specific indication

and give the user a short summary of current guidelines.

At a broader level this design problem relates to the speed and accuracy dimensions of clinical decision making, which is often solvable by triage, heuristics, decision trees and similar techniques. After initially testing these techniques with limited success, it became clear that offering a list of summarised clinical indications and separate learning materials was a more effective design in this case. It was also a more appropriate design as the purpose of the app shifted from the initial aim of providing a quick decision support to instead offering educational materials where solving the time/accuracy trade-off was a less pronounced design goal. The main stakeholders involved in the project are presented in table 4.4.

Table 4.4: Stakeholders in the SBC app project.

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Patients requiring blood tranfusion, and their carers.
Healthcare professionals (doctors, nurses, blood bank staff and others).
The core research team (PhD candidate and supervisory team).
Collaborative partners, contributors and research participants.
Various local, national and international organisations and communities of practice who share an interest in the issue.

## **Part II**

# **EMPIRICAL STUDIES**



# **Chapter 5:**

## **Study 1: Review of an Existing Transfusion App**

This study offers a critical review of a recently published app in transfusion medicine based on interviews and usability testing with a small group of healthcare practitioners. The app under review aims to promote conservative use of platelets and targets clinicians who prescribe blood components.

The chapter begins by introducing the rationale for the study together with the objectives and methods. In the results section, participants comments are analysed thematically and the clinical content, dose calculator and usability of the app is discussed in detail. The chapter concludes by reflecting on the key issues that the study has raised and the extent to which they may be applicable to the design of the Special Blood Components app, as well as medical apps more generally.

## 5.1 Introduction

As was noted in chapter two, there is a general shortage of evaluations of medical apps undertaken by researchers who are independent from the development team. This has resulted in a situation where the use of many medical apps is unsupported by evidence.

The lack of published independent evaluations extends to other forms of eHealth initiatives too, which often lack high quality evidence supporting their use (Black et al., 2011). This failure to evaluate existing apps not only reduces their credibility, but is also a lost opportunity to identify and correct problems. For example, usability issues, inaccurate information or unintended impacts could be corrected in software updates.

Given the dearth of evaluations of healthcare information technologies generally, and blood transfusion apps in particular, the purpose of this study was to identify existing apps in transfusion medicine and review them with potential target users. The rationale for the study was to learn from what has gone before and to identify lessons, such as good practices and pitfalls, that could inform the design of the Special Blood Components app. Specifically, the study sought to answer two related research questions:

1. What strengths and weaknesses do practitioners identify in an existing app aiming to improve a specific area of blood transfusion practice?
2. To what extent could their observations transfer to other medical apps?

## 5.2 Methods

Searching for suitable apps to review in the Google and Apple app stores revealed that there were few appropriate apps in transfusion medicine at the time of study (April 2013). After discovering the recently published web-based “Platelets app” (NHSBT, 2013), which is unavailable through the app stores, it was apparent that it would be a suitable candidate to review.

The Platelets app was a good comparator to the Special Blood Components (SBC) app for several reasons. It had a similar purpose and audience since it aimed to improve the use of blood components and targeted healthcare practitioners. Like the SBC app, it was designed as an interoperable web app for a range of devices and platforms and appeared to be based on current UK national transfusion guidelines.

To provide some context, the platelets app (shown in figure 5.1) is promoted as a bedside tool to aid clinical decision-making during the prescription of platelets and aims to reduce the inappropriate use of platelets (Estcourt et al., 2013). It was developed by a team at NHS Blood and Transplant (NHSBT), but had not been evaluated in detail previously. Members of the development team explained that the Platelets app had been created under challenging time and budget constraints. They also hoped to secure additional funding to continue its development.



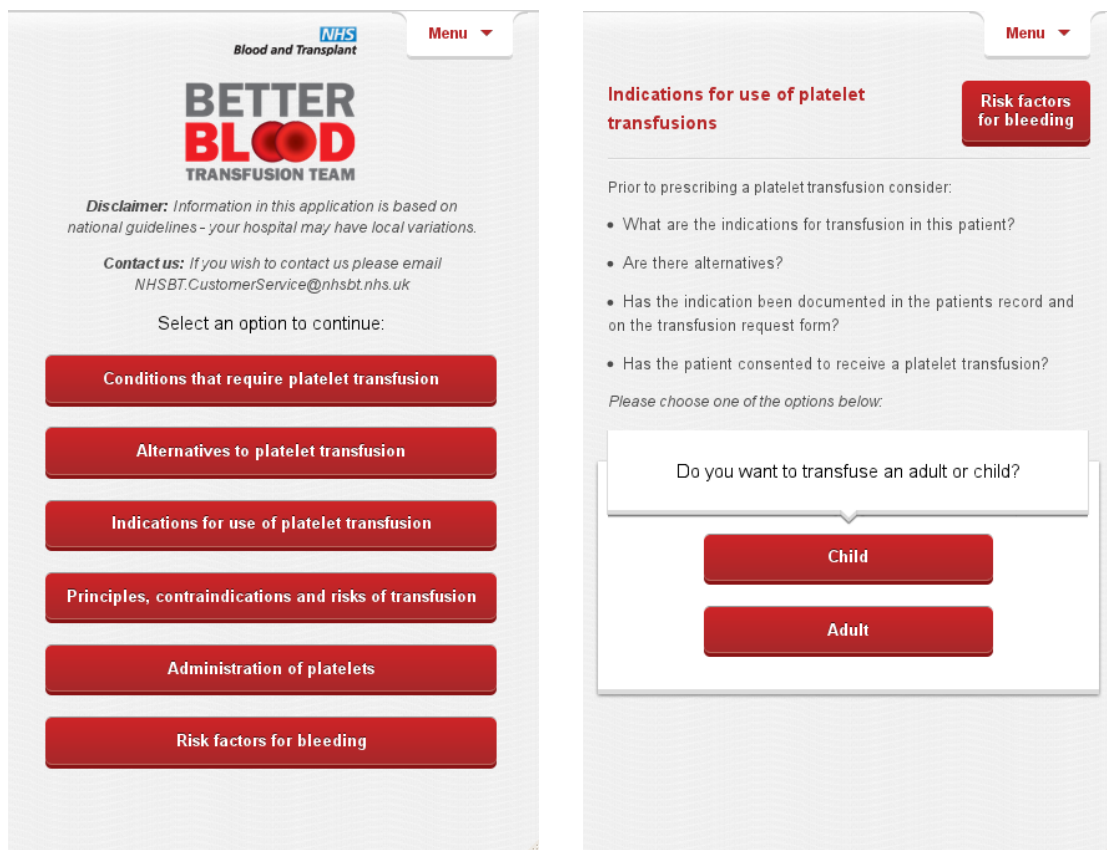


Figure 5.1: Screenshots of the NHSBT Platelets app. Left: welcome screen with the main menu options. Right: the “indications for platelet transfusion” page offers the user recommendations for prescribing platelets to adults or children. The app is available at: [http://hospital.blood.co.uk/safe\\_use/platelet\\_education\\_resources/bbt/](http://hospital.blood.co.uk/safe_use/platelet_education_resources/bbt/)

About ten healthcare practitioners involved in blood transfusion were identified and invited via the Scottish National Blood Transfusion Service (SNBTS) to take part in the study. Seven participants agreed to participate on the basis of interest in the topic and meetings were arranged with three haematologists (1 consultant and 2 registrars), three anaesthetist consultants and one transfusion practitioner nurse. In addition, the medical advisor to the research project took part in the interviews.

Evaluation was conducted using four semi-structured interviews (Gillham, 2005). The anaesthetists and haematologists were interviewed separately. To accommodate the commitments of participants, two interviews were group interviews (focus groups), with two and three participants respectively. The remaining were single interviews. Interviews lasted between one and two hours, and took place in the hospital workplace of participants.

Abridged “technobiographies” (Kennedy, 2003, 129) are summarised in table 5.1 and illustrate the experience of information technologies that the participants shared. During the interviews, participants were encouraged to freely explore the Platelets app using a supplied iPad and to “think aloud” while doing so. Thinking aloud is a simple and widely used technique for identifying usability problems:

“By verbalizing their thoughts, the test users enable us to understand how they view the system, which makes it easier to identify the end users’ major misconceptions [—] revealing why users do something; providing a close approximation to how individuals use the system in practice; [—] early clues can help to anticipate and trace the source of problems to avoid later misconceptions and confusion in the early stage of design.” (Holzinger, 2005, 73)

The interviews were based on the schedule in appendix A.2, but diverged from this as required. As can be seen in the interview schedule, in addition to reviewing the Platelets app, all participants were asked to test and give feedback on the first prototype of the Special Blood Components app. Results from this activity is discussed in study two (the next chapter).

Table 5.1: Role, age range and thumbnail technobiography of participants. Names have been changed to preserve anonymity.

Alias	Role	Age	Thumbnail technobiography
Andrew	Medical adviser to project	65+	Proficient user of smartphone and tablet devices. Present during all interviews.
David	Consultant anaesthetist	50-64	“I am not an IT freak. I have just got a basic Android phone, and the only app I have is for bus tracking. My son loaded it for me.”
James	Consultant anaesthetist	50-64	Android user who uses his smartphone in clinical practice. During the interview, he sets up a temporary Wifi access point.
Jane	Consultant haematologist	50-64	iPhone owner. She confidently used an app on her phone to make a calculation during the interview. Touch-types on the computer keyboard.
Laura	Transfusion practitioner	50-64	Knowledgeable about several hospital information systems which she uses to monitor blood requests and incidents.
Mary	Haematology registrar	20-34	Enthusiastic about medical apps: “I think apps are the perfect form of flowchart. Because you just tick ‘yes’, ‘no’, ‘next screen’, ‘yes’, ‘no’, ‘next screen’. Much quicker and its in your pocket.”
Neil	Consultant anaesthetist	35-49	Develops web based software in his spare time. His brother is a software engineer and they work on web projects together.
Sarah	Haematology registrar	20-34	Confident iPad user.

Additionally, the anaesthetist consultants were invited to explore and comment on a free game-based learning app developed by the Mayo Clinic called “TransFuse”. One of the haematology registrars was also asked for her views on the Australian Blood Service’s website about the indications for irradiated blood. However, the clinicians’ feedback relating to the TransFuse app and the Australian Blood Service’s website is outside the scope of this chapter.

The interviews were recorded, transcribed, coded and analysed by hand, loosely following a grounded theory approach (Glaser and Strauss, 1967; Strauss and Corbin, 1998). After reviewing the transcript and coding patterns several times, participants’ comments were organised into four themes, which were used to structure the results and discussion:

1. Overall impression.
2. Clinical content.
3. Dose calculator.
4. Usability issues.

## 5.3 Results

In this section, I present and discuss the comments raised by the participants. On the whole, the reception of the Platelets app was mixed. Participants felt that the app addressed an important issue, but that there was scope for improvement:

“There’s potential for it being useful [...] ideally [as part of] a transfusion app incorporating red cells, platelets and plasma. [...] from the point of view of restricting inappropriate use of red cells, plasma and platelets, actually having an app that has fairly restrictive thresholds that people may look at once or twice might just help the culture of avoiding excessive transfusions.” (James, consultant anaesthetist)

“I personally haven’t fallen in love with it. I think it is too cumbersome. And it doesn’t necessarily give the right answer.” (Jane, consultant haematologist)

“I wouldn’t find it very helpful to be honest. I would probably reject that at first pass, and probably just ask a friend or something.” (David, consultant anaesthetist)

To better understand the reasons why respondents held these views, I will discuss their comments related to the quality of the clinical content of the app, problems with the built-in platelet dose calculator and issues related to usability.

### 5.3.1 Clinical content and presentation

Participants identified several issues with the contents of the Platelets app, ranging from inaccuracies of the clinical recommendations and possible omissions to failing to accommodate user preferences about how the information in the app should be written, structured and presented.

For instance, the thresholds for prescribing platelets is perhaps the single most important information that users of the app are likely to look for. However, the value and provenance of the transfusion threshold presented in the app was unclear:

“Where did the 75 threshold [ $75 \times 10^9/L$  platelet count] come from? [...] No guideline that I have read, as far as I remember, has ever mentioned 75. There’s 50, 100 and 80. 75 is completely random, not necessarily wrong, but random.” (Jane, consultant haematologist)

“I’m not sure where these numbers come from. For example, patients with multiple trauma [are recommended a] platelet count of a hundred. There are European guidelines for patients with trauma which recommend keeping the platelet count above fifty. [—] So I am not sure if a hundred is a BCSH [British Committee for Standards in Haematology] thing?” (James, consultant anaesthetist)

That said, another participant found the app’s threshold for epidural anaesthesia acceptable, as illustrated in this following extract:

“[Let’s say] I want to transfuse pre-procedure, except eyes and brain. So this is like a central line, a procedure we would do. Put a line into someone’s neck. We often worry about platelet count because they might bleed.” (David, consultant anaesthetist)

[looks up threshold in app]

“Ah, there we go. Oh, epidural anaesthesia. Oh, that’s good. 80 [...] All other procedures 50. That’s fair enough.” (David, consultant anaesthetist)

### **State the aim and sources used by the app**

Although the app had been designed to promote conservative use of platelets, one participant felt that the purpose was unclear because the app’s thresholds were higher than those used in current practice:

“Is the reason for this app to help people decide when to give platelets [...] because there is a perception that we’re giving platelets inappropriately and [the app is trying] to stop it?” (James, consultant anaesthetist)

“My sense is that it was the latter. But I don’t know the full background.” (Andrew, medical advisor to project)

“I’m sure that’s true, but some of the thresholds there are actually higher than we’re sometimes following.” (James)

Transparency about the objectives and sources that an app draws on is important to allow users to independently verify the recommendations embedded within an app, and make an informed choice about whether to use the app or not. Participants recognised that universal agreement on thresholds may not be feasible, and suggested that the app should cite its references:

“The numbers are always going to be controversial.” (James, consultant anaesthetist)

“Well yes, but if they are controversial and the controversy lies within a range of numbers, then the app needs to reflect that. Or if there is a UK guideline which is sensible in terms of the current play of the controversy, they should reflect that. But in something as dynamic as this it needs to be very clear about what [it is based on].” (Andrew, medical advisor to project)

### **Offer clear and consistent information**

In terms of the presentation, participants expressed uncertainty about whether the value stated in the app represented the target platelet count or the threshold for prescribing platelets:

“Prophylactic use involving eyes or brain... [Does it mean we should] transfuse if it is a hundred or less? Or aim for a hundred?” (Mary, haematology registrar)

“We know what it means, but that implies if they are at a hundred you need to get them platelets. Rather than that if they are nearly a hundred you are fine.” (Jane, consultant haematologist)

“That’s a threshold value. If below ‘x’, give platelets.” (Andrew, medical advisor to project)

“It should say less than a hundred rather than a hundred.” (Jane)

The need to clarify whether the platelet count value in the app is a minimum or maximum value was echoed by one of the anaesthetists. Furthermore, in the recommendations for massive bleeding, both the minimum and maximum values were stated in the app. This is different from the single platelet count threshold that is used in the table with indications. Again, the decision to include two values led to some confusion:

“Keep platelets above 50 and aim for 75... I find that a little bit difficult. I want to have a target. If I keep it above 50, then I am happy with 51. If I want 75, then I aim for 75.” (James, consultant anaesthetist)

It would perhaps remove some confusion if the same value, or set of values, were presented consistently for all indications, with appropriate labels. One of the anaesthetists also commented that some of values were imprecisely labeled:

“That [table column with threshold values] should say platelet count or threshold platelet count. [...] One adult unit. It should say one unit of platelets. You really need to be clear about these things.” (David, consultant anaesthetist)

### **Help the user complete their task**

For indications where it was not possible to state a threshold, it was not clear why the indication was included in the app since that information did not appear to help the user complete their task:



[Reading indication for irreversible bone marrow failure]:

“So it is not possible to state threshold, which is probably right.” (Neil, consultant anaesthetist)

“Yeah, [for] that one, irreversible bone marrow failure. So it’s not very helpful, is it?” (David, consultant anaesthetist)

This raises a broader question about how apps should deal with cases where there are no clear recommendations or where a treatment is not indicated. The extent to which this kind of information is included or left out is an important editorial judgement that should be made explicit. Furthermore, to make the recommendations easier to apply, some participants felt that the app should be more prescriptive:

“But [the app] doesn’t actually tell me what I am supposed to be doing.” (David, consultant anaesthetist)

The following dialogue, drawing on a hypothetical scenario involving an obstetric patient, illustrates how the recommendations provided by the app were sometimes difficult to interpret and caused confusion:

“All other procedures except epidural stays at [a platelet count of  $50 \times 10^9/L$ ]. Interesting, I thought the guidelines said [80]... it doesn’t tell you actually if it is [appropriate for] an obstetric [patient]? No. If it is for anything else, yes.” (Jane, consultant haematologist)

“I thought they [the guidelines] said 80?” (Mary, haematology registrar)

“But if you need to support an obstetric [patient] [with a platelet transfusion] then you wouldn’t [do an epidural].” (Jane)

“Oh sorry. Because if it wasn’t 80 and above?” (Mary)

“For an obstetric, as far as I can remember, if you had to support to get to 80, you wouldn’t do epidural.” (Jane)

“But then this is suggesting that if you are running at 80 and you’re doing an epidural, you need to give platelets. Because this is the prophylactic use [pre-procedure except eyes and brain]. Isn’t that what it is saying?” (Mary)

The app contains pages with guidance about indications for platelet transfusion and alternatives to platelet transfusion. At the stage of prescribing platelets in the app, the user is asked questions about these topics, but there is no link back to the guidance.

The user can therefore easily miss the information, as this example shows:

[reads off screen:] “Prior to prescribing platelets for transfusion, what are the indications for transfusion, are there alternatives? But then it doesn’t really help answer those, does it?” (Sarah)

In the context of surgery, two of the anaesthetists made the general point that thresholds are of limited use when a patient’s condition is changing quickly, or when antiplatelet drugs are used:

“The other issue with major bleeding is of course the fact that with your platelet count, by the time it is back, the patient has either lost a lot of blood or you’ve given some treatment. So it is not necessarily particularly relevant.” (James, consultant anaesthetist)

“The thing about these thresholds is [...] you’re not dealing with a static situation [...] it is not as clear cut as an one snapshot in time. What has happened, what is happening now and what is going to happen?” (Neil, consultant anaesthetist)

### **Take existing working practices into account**

Further to the thresholds, participants identified issues with other parts of the contents of the app. For example, the app recommends taking a full blood count after transfusion, but this does not reflect current clinical practice according to the participants:

“It is a bit odd that they suggest that [you should] remember to take FBC [full blood count] after transfusion has been completed. That is not the clinical practice, only if there’s [a special reason]... We wouldn’t usually ask for that.” (Mary, haematology registrar)

“It depends on what you are doing. If you are going to do an epidural I think it would be common sense to confirm that what you have done has had the necessary effect. But if, for example, the patient is having [...] surgery [or] splenectomy, you’d give them platelets and run with it.” (Jane, consultant haematologist)

“And also it says this exact same sentence with every single indication, even with the prophylactic with a platelet count of 10. Which we don’t do.” (Mary)

Furthermore, in the section in the app dedicated to alternatives to platelet transfusion, participants felt the prescription of DDAVP (Desmopressin, a drug that reduces bleed time) should involve haematology:

“[for patients with uraemia] consider DDAVP with specialist renal advice. Really? I think that [should be] haematology.” (Jane, consultant haematologist)

“Well, I see they’ve got specialised haematology advice down here [next item in list].” (Andrew, medical advisor to project)

“For inherited platelet function disorders only.” (Mary, haematology registrar)

### **Signal important omissions**

On the issue of relevant medical treatments, antiplatelet drugs, such as aspirin and Clopidogrel, are widely used and can cause excessive bleeding. However, this topic is not included in the app:

“What I haven’t found yet is antiplatelet drugs which in surgical patients, particularly in cardiac surgery patients, is a huge issue, particularly aspirin and Clopidogrel. Which obviously isn’t picked up by the blood count. Some people are using point of care aggregometry or modified thromboelastography to get an assessment of the drug effect, but in terms of bleeding during surgery that is a huge issue.” (James, consultant anaesthetist)

The app contains instructions about how to carry out platelet transfusions. For example, it states the rate of transfusion and that platelets can be given through a

standard set. However, it does not answer if it is acceptable to reuse a set that has had red cells given through it, a question that one of the clinicians raised:

“One thing that isn’t here and perhaps this is something you could help me with. It is often said that platelets shouldn’t be given through a set that has already had red cells given through it. But I don’t know why and it is not in here. So I am not sure if it is important.” (James, consultant anaesthetist)

“I personally don’t think it is important. There is no evidence for it, but I think it is still in the BCSH guidelines. [...] So I think that’s probably an omission.” (Andrew, medical advisor to project)

The app also does not provide information about how the rate of transfusion would change in a paediatric setting (20-30ml/kg/h) (BCSH, 2003, 17), nor does it link to the guidelines so that the user could easily find out for themselves. Based on these comments, it would be useful if the app stated clearly what was included, and any notable limitations, such as anti-platelet drugs.

### 5.3.2 Platelet dose calculator

The dose calculator feature initially excited participants. Perhaps because it can be confusing as this anecdote where the consultant haematologist tries to explain platelet dosing to a registrar illustrates:

“I tried giving a unit of platelets recently and heard this registrar say:

*‘Well, this transfusion consultant wants to just give us a unit [although] I explained that it is 15ml per kilo!’.*

I tried to explain to the [registrar] that 15ml per kilo is much more than a standard unit [150-300ml].” (Jane, consultant haematology)

However, participants discovered several issues with the dose calculator. The list of indications do not update to reflect the entered weight. For example, the indications for neonate and infants are still displayed for a 17kg child:

“Go back to the original list. Did you go into child?” (Jane, consultant haematologist)

“No, not yet. ” [taps on 'child' button] (Mary, haematology registrar)

[on seeing weight input box:] “Oh okay, interesting. ” (Jane)

“We’ll just pick a small one” [types in 17 kilos] (Mary)

“Prophylactic, patent not bleeding” [taps on 'prophylactic without risk factors']. (Mary)

“That’s quite an interesting idea.” (Andrew, medical advisor to project)

“Calculation 1 unit of platelets.” [reads out indications for neonate and infants] (Mary)

“None of which are likely to weigh 17 kilograms.” (Andrew)

Further testing revealed that no validation is done on the entered weight. A typo or simple user error, such as accidentally entering non-numeric character, leads to an incorrect recommended dose. For example, entering “2kg” erroneously returns one adult unit of platelets, a dangerously high dose. Table 5.2 contains a few simple test cases and the recommended doses returned by the app. A sample calculation is shown in figure 5.2.

Table 5.2: Recommended doses for valid and invalid test cases returned by the Platelets app, last tested 26 October 2015.

Input (weight [kg])	Recommended dose [ml]	Correctness
15 and over	1 adult unit (150-300ml)	Correct
12	120-240 ml	Correct
6	60-120 ml	Correct
3	30-60 ml	Correct
0	0 - 0ml	Incorrect (should fail)
-2	-40 - -80	Incorrect (should fail)
Non-numeric (e.g. "2kg")	1 adult unit	Incorrect (should fail)

The figure consists of two side-by-side screenshots of the Platelets app interface.

**Left Screenshot:** The app shows the 'Indications for use of platelet transfusions (continued)' screen. A red button labeled 'Risk factors for bleeding' is visible. Below, it says 'You have selected "Child"'. A text input field contains '10kg' with a 'kg' unit label. A red 'Submit weight' button is at the bottom.

**Right Screenshot:** The app shows the 'Indications for use of platelet transfusions (continued)' screen. A red button labeled 'Risk factors for bleeding' is visible. Below, it says 'You have selected "Child"'. A text input field contains '10kg kg'. A red button labeled 'Submit weight' is at the bottom. Below this, it says 'You have chosen Therapeutic use'. A red button labeled 'Change indication' is at the bottom. Below this, it says 'Calculation: 1 Unit of Platelets'. Below this, it says 'Remember: Take a FBC after the platelet transfusion has been completed. A sample taken 10 minutes after the transfusion is equivalent to a 1 hr increment.' Below this, there is a table with two rows: '\*All patient indication categories. If patient has major bleeding keep platelet count above 50x10<sup>9</sup>/L, aim for 75x10<sup>9</sup>/L' and '75 x 10<sup>9</sup>/L'; 'For patients with multiple trauma or CNS injury' and '100 x 10<sup>9</sup>/L'. Below the table, it says '\* TTP and HIT platelet transfusion contraindicated unless life-threatening haemorrhage'. Below this, it says '• If patient has clinically significant but not major bleeding give a standard platelet dose and reassess'.

Figure 5.2: Example of an erroneous platelet dose calculation. Left: the user inputs the weight a paediatric patient, specifying kilograms. Right: The app incorrectly returns a recommended dose of 1 adult unit. A simple bug in the calculator (failure to validate input data) causes non-numeric values such as "10kg" to always return 1 adult unit.

Because the app is web-based and relies on Javascript, it is easy to inspect the code and identify the incorrect portion. In this case, the error is in the `setChildWeight` function:

---

```
1 setChildWeight: function () {  
2   this.weight = $('#childs-weight-textbox').val();  
3   /*  
4     Three unimportant lines removed to improve legibility  
5   */  
6   this.calculation = (this.weight < 15) ? (this.weight *  
       10) + ' - ' + (this.weight * 20) + 'ml' : '1 Unit of  
       Platelets';  
7   $('#jsCalculation').html(this.calculation);  
8 }
```

---

On the second line, the value entered by the user is retrieved without any kind of verification that the value is within a valid range or of a correct data type (i.e. a number). On line six, this unvalidated value is used to generate a recommended dose calculation, which is then returned to the user on the next line.

The conditional (ternary) statement on line six reads: if the entered weight evaluates as below 15 kilos, the recommended dose is calculated as a range, starting from the weight multiplied by ten to the weight multiplied by twenty. However, if the condition evaluates as false, the dose always defaults to one adult unit.

The programmer's intention was to ensure that weights over 14 kilos yields one adult unit. However, as Javascript is a loosely typed language, code execution will not stop if a user enters a bad value, such as non-numeric text string when a numeric value is expected. Instead, the Javascript interpreter will continue to evaluate the condition.

In this case, this results in a behaviour where if a weight is entered as “2kg” (the ‘kg’ letters makes this value a Javascript string and not a numeric value), the condition will evaluate as false and the code will incorrectly return a recommended dose of one adult unit. This behaviour can easily be corrected by checking that the entered value is a valid numeric value, for example using Javascript’s built-in function `isNaN()` where NaN stands for “not a number”. The entered value could further be validated by checking that it is within an acceptable range (e.g. non-negative).

These findings highlight the importance of studying interactive cognitive aids in their context of use context to uncover problems and suggest design improvements (Furniss et al., 2015, 338). Moreover, the dose recommended by the app does not change depending on whether the patient is bleeding or if it is for prophylactic use, although the national guidelines suggest it should:

“When platelets are given therapeutically to treat active bleeding, a larger dose of platelets may be indicated; the dose and frequency of administration depends on the individual circumstances, and it is not possible to give general advice.” (BCSH, 2003)[17]

The BCSH guidelines also recommend 10-15ml/kg, not 10-20ml/kg, and the cut off point for one adult unit is 20kg, not 15kg (ibid):

“One platelet concentrate is usually given to most adult patients. In small children (under 20 kg), 10–15 ml/kg up to the adult dose of one platelet concentrate is used; in older children, an adult dose of platelets should be used.”



### 5.3.3 Usability

Interactive apps running on smartphones and tablets place different demands on the design compared to desktop computer software or medical guidelines. For example, apps should be easy to use on small screens, and they should allow users to stop and resume a task easily. This is important in situations where the user is splitting their attention between other tasks and may be distracted, which is likely when using mobile devices. Thus, manufacturers of mobile devices have issued guidance for creating high quality apps. These include the iOS Human Interface Guidelines ([Apple, 2015](#)) and the Android design documentation ([Google, 2015](#)).

#### **Define purpose and scope of the app**

A key point raised in both iOS and Android design guidelines is the rule that an app must have a clear, narrowly defined purpose. The clinicians who evaluated the Platelets app expressed some confusion about its purpose:

“I’m sometimes not sure what [the purpose is]. Is the reason for this app to help people decide when to give platelets?” (James, consultant anaesthetist)

“It is almost like a sort of major haemorrhage protocol isn’t it? [–] It is not totally clear who it is aimed at. [–] Maybe it is more of an educational thing really.” (Sarah, haematology registrar)

The iOS Human Interface Guidelines stresses the importance of defining the scope of the app, such as supported tasks and target audience ([Apple, 2013](#))[9]:

“When you’re starting with an idea for an app, it’s crucial to decide precisely which features you intend to deliver, and to whom. [—] It’s essential to keep the user experience uppermost in your mind as you design every aspect of your app, from the way you enable a task, to the way your app starts and stops, to the way you use a button.”

Thus, users would likely benefit if the Platelets app communicated its purpose and scope more clearly, such as what topics are within and outside its scope, who the intended audience is and where in the transfusion process the app should be used. Clarity about the purpose and scope would also make it easier for the user to assess if the app is likely to meet their needs. This could take the form of a brief mission statement shown on the home screen of the app.

### **Prioritise the key task**

The design guidelines also highlight that an app should have one or more “killer” or “hero” task that users of the app are likely to want to carry out. The app must be designed in such a way that users can complete these tasks efficiently, and with minimal frustration. Most participants thought that the main purpose of app was to show indications and thresholds for platelet transfusions. One of the first questions asked about the Platelets app was: “So does it give a platelet count?”

The design should therefore make this feature much more prominent and faster to complete. For a new user, it is not obvious that the thresholds are listed on the “indications” page because they have to go through many steps before they can see the thresholds, as this extract from the interviews demonstrates:

[After opening 'conditions that require platelet transfusion' page:] "To me, if I read that and I am a junior doctor and I have a patient with a platelet count of 40 and it is bone marrow failure, should I be giving them platelets? [...] At this point [...] it's not saying." (Jane, consultant haematologist)

[suggests pressing 'Indications for use of platelet transfusions'] (Mary, haematology registrar)

"Yeah try that." (Jane)

[taps button and skims screen:] "Who would you like to transfuse..." (Mary)

[taps 'adult':] "If for prophylactic use, give 1 adult unit and reassess patient." (Mary)

"If you click on prophylactic does it give you [the threshold value]?" (Jane)

[Expands section which shows two new buttons:] "It doesn't give a platelet count! [taps the first of the newly appeared buttons] *Ah, it does there. Finally!*" (Mary, emphasis added)

"My goodness! What did you guys think of this? Because for me I would expect ... you had to go through too many pages to get to anything that tells you whether it is yes or no." (Jane)

The app should make it very clear how to find the platelet count thresholds. Everything else should be given lower priority:

"If the question is: should you give platelets, how much and when? Then maybe you should concentrate on that". (James, consultant anaesthetist)

### **Structure the app around the key task**

It is important to identify the key task that the app must get right to please most users.

To achieve this, the app must be structured so that the user can easily carry out the task they have in mind. This means understanding the user's way of thinking, and reducing the gulf of execution (Norman, 1988): "The gulf is small when the system

provides information about its state in a form that is easy to get, is easy to interpret, and matches the way the person thinks of the system" (Norman, 1988, 51).

Participants' comments gave the impression that the app had been written without sufficient input of an experienced, practising clinician, familiar with the daily ins and outs of platelet therapy. The app takes the user through the stages of platelet transfusion, from conditions requiring platelets, alternatives, indications, counter-indications, administration and risk factors for bleeding. But one participant commented that the app had the wrong starting point and suggested an alternative flow:

"It is almost starting in the middle of the question, because you really want it to be [structured like this]... Patient with low platelets. Patient who is bleeding. Or patient who is for a procedure." (Sarah, haematology registrar)

"Then, maybe if you picked patient who is bleeding, it could say normal platelet count, low platelet count or whatever. And if you pick normal platelet count, it [would ask] has the patient been given anti-platelet agents? Still consider giving platelets. If not, [platelets are] probably not required." (Sarah)

"And then if you picked, patient with low platelets, it would take you through: are they low because they have an irreversible bone marrow failure; or are they low because they have had chemotherapy [...] Or is it Heparin, or something all together different." (Sarah)

"Or then it could say... Patient going for procedure. What is their platelet count? What is the procedure? Is it one that is high risk or low risk for bleeding. Have they got other issues, such as antiplatelets agents? (Sarah)

### **Avoid getting in the way**

Medical apps are typically accessed for short periods of time and must therefore allow users to complete their tasks quickly. Comments from participants indicate that the app could be made more succinct:

“It looks as though you need to sit down and really work it through. It wouldn’t be anything that you’d be looking at in the ward.” (Laura, transfusion practitioner)

“Some people like things that are text based.” (Andrew, medical advisor to project)

“Not when people are panicking.” (Jane, consultant haematologist)

“Yeah, there’s too much to read.” (Mary, haematologist registrar)

Moreover, participants felt that the app contains information which was superfluous to the core task of determining indications and thresholds for platelet transfusion:

“[The app] has clearly come from a sort of blood transfusion background with lots of caveats about [making] sure you’ve got consent and recorded things in notes, and filled in forms. [All of] which are important. But [...] they [the instructions] give way to some of the flow. [...] Getting consent and filling in paperwork is for somewhere else.” (James, consultant anaesthetist)

“If you are someone from another specialty [than haematology], you are like: ‘why are they asking me about risk factors for bleeding’, ‘what has that got to do with it?’ Whereas maybe what you want to say is something more to do with your platelet threshold for transfusion.” (Sarah, haematology registrar)

### **Simplify navigation**

In terms of navigating the app, it provides some cues about where the user is through page headings and occasionally through vertical button breadcrumbs. However, the app is sufficiently complex for a new user to get lost:

“Where are we?” (Jane, consultant haematologist)

“We’re in therapeutic use, which is the last of the indications.” (Mary, haematology registrar)

The navigational structure could be made simpler and clearer, for example by numbering headings and subheadings and by exposing page hierarchy. One of the most important navigational aids is the back button, which is missing from some screens:

“Can I go back? Because I am not sure what I clicked to get to this.” (Jane, consultant haematologist)

“So how do I get back? There isn’t a back button, which is bad. Because you get kind of stuck in the middle of it, going around in circles.” (Sarah, haematology registrar)

In rare combinations, the back button is present, but non-functional (nothing happens when you click it). For example, the back button on the “risk factors for bleeding” page is not working when the user is coming from a page showing a calculated child or adult platelet dose.

The app lacks a “home” button and there is no way of getting to the front screen once you leave it, except by reloading the app. Although the quick menu shows largely the same information, the decision to not provide a method of getting back to home screen can make the user feel that they are missing something:

“It [the menu] doesn’t look the same as before. What have I done?” (Sarah, haematology registrar)

More consistent use of navigation buttons would improve user experience. Google and Apple design guidelines have recommendations for handling navigation. The user is likely to be familiar with these conventions and the app should seek to emulate these. For example, by putting the back button in the top left corner of every page.

## 5.4 Discussion

Although the app garnered a mixed reception, most participants felt that it was relevant and addressed an important issue. It was perceived as potentially improving access to thresholds and dosing advice, and could perhaps contribute to improving prescribing culture. However, a number of important weaknesses were identified in the app, making it less likely to be used. The interviews revealed a range of issues to do with the content, dose calculator and usability of the Platelets app.

### 5.4.1 Thresholds and recommendations

The thresholds for prescribing platelets is something that users of the app are likely to look for, but the value and provenance of the platelet threshold for major bleeding in the app ( $75 \times 10^9/l$ ) was questioned by participants. Although the app promotes conservative use of platelets, some thresholds were sometimes higher than those used in current clinical practice. As universal agreement on thresholds is unfeasible, the app should cite its sources.

Additionally, the presentation of the thresholds was sometimes unclear. For example, there was confusion about whether the states values represented the target platelet count or threshold for prescribing platelets. In the recommendations for massive bleeding both the minimum and maximum values are given. This was different from the single platelet count threshold used in the indications table.

It was also not always clear how the recommendations should be interpreted. For example, the app recommends that a full blood count should always be taken after transfusion, but this does not reflect current clinical practice. Another problematic area is antiplatelet drugs, such as aspirin and Clopidogrel, which are widely used and can cause excessive bleeding. However, the app's recommendations did not appear to take this aspect into account at any point.

#### **5.4.2 Potential for errors**

The calculator feature, which initially excited participants, recommends one unit of platelets for adults and calculates an adjusted dose for children based on weight. It has a threshold set at 15kg. If the weight is above this, the dose defaults to one adult unit. If it is below, the dose is calculated as a range in milliliters based on the weight. Participants found some issues with the calculator. For paediatric dosing, the list of indications are not updated to reflect the entered weight. For example, the indications for neonate and infants are still displayed for a 17kg child.

More seriously, no validation is done on the inputted weight value. A typo, such as an accidentally entered non-numerical character, could lead to an incorrect dosage being recommended. For example, entering "2kg" erroneously returns one adult unit. This has potential to lead to medical error and serious patient harm. Additionally, the dose recommendation does not change depending on whether the patient is bleeding



or if it is for prophylactic use, although the national guidelines on the use of platelets suggest it should. Furthermore, the same guidelines recommend a 10-15ml/kg dose for children under 20kg (not 10-20ml/kg for children under 15kg as recommended by the app).

### 5.4.3 User experience

Smartphones and tablets place different demands on design compared to desktop computers or printed guidelines. Apps must be easy to use on small screens, be optimised for short interaction time and work in situations where the user may be distracted. Mobile app design guidelines therefore stress the importance of clearly defining the scope, such as supported tasks and target audience. However, participants expressed confusion about the aim of the Platelets app.

Thus, users would benefit from clearer information about the purpose of the app, what is included and excluded from its scope, who the intended audience is and when in the transfusion process the app should be used. This could take the form of a brief mission statement at shown on the home screen of the app. Clarity about the purpose and scope would also make it easier for the user to assess if the app is likely to meet their needs. Indeed, one of the first questions asked about the app was “so does it give a platelet count?” The design should make this feature much more prominent and faster to complete. For a new user, it is not clear that the “indications” page is where to look

for thresholds, nor that they have to go through several steps to get to the thresholds.

Furthermore, there was an impression that the app had been written without sufficient input from an experienced, practicing clinician. Indeed, one participant commented that the app had the wrong starting point and suggested an alternative flow based on more clinically focused questions. Medical apps are typically accessed for short periods of time and to allow users to complete tasks quickly, they must follow the user's way of thinking to reduce the gulf of execution (e.g. make it clear to user how to use the app to achieve the task at hand).

In terms of navigation, the app provides cues about where the user is through page headings and occasionally through vertical button breadcrumbs. However, the app is sufficiently complex for a new user to get lost. The navigational structure could be made clearer. For example, by numbering headings and subheadings, and exposing menu hierarchy. One of the most important navigational aids is the back button. This was missing on some screens and occasionally it did not work.

The app also lacked a "home" button so there was no way to get to the front screen once you leave it (other than reloading the app). Although the quick menu shows largely the same information, the decision to not provide a method of getting back to home screen made user feel that they were missing something.

## 5.5 Conclusion

The objective of this study was to review an existing blood transfusion app targeting healthcare practitioners in order to learn from what has gone before. The study, among the first independent reviews of an app in transfusion medicine, revealed notable weaknesses in the clinical content, dose calculator and usability of the NHSBT Platelets app. The findings highlight how medical apps released with bugs and usability problems are not only likely to be rejected by practitioners, but could potentially also contribute to medical errors.

This study demonstrated that it is relatively straightforward to identify weaknesses in medical apps and that reviewing existing interventions can identify important design lessons, such as following conventions that users are familiar with. Table 5.3 summarises the main areas of improvement and possible enhancements. Most of these are general points that transfer readily to the design any medical app.

This was a small qualitative study conducted without giving participants an explicit clinical task, and reflecting the view of mainly senior clinicians. It did not involve junior doctors or medical trainees who are also in the target audience for the app. With these limitations in mind, practitioners' comments made it quite clear that app could be significantly improved. Furthermore, unless the budget, skills and organisational processes are in place to detect bugs and roll out software fixes, it can be challenging to make corrections in a timely manner.

Table 5.3: Summary of areas of improvement for the Platelets app.

Maximise task efficiency and minimise user frustration	Promote the key task (looking up thresholds). Make this task more obvious and faster to complete.
Validate the dose calculator	Check input to prevent erroneous results. Develop test cases to verify accuracy of the calculation. Show the user how the resulting dose was derived.
Content and structure	Add a brief mission statement to clarify the purpose and scope of the app. Label and present thresholds consistently. Make recommendations more explicit. Layout information according to the users' way of thinking.
Usability	Simplify the navigational structure (possibly by reducing scope); Ensure navigation buttons are present on every page and functional.
Evidence base	Add references to allow users to verify of the source of the information.

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## **Chapter 6:**

# **Study 2: Concept Validation of the Proposed App**

This chapter explores challenges pertaining to the use of irradiated and Cytomegalovirus (CMV) negative blood components through the perspectives of healthcare practitioners involved in blood transfusion at two Scottish hospitals. The study also solicited their feedback on the initial working prototype of the Special Blood Components (SBC) app intended to address this topic.

The chapter begins by detailing the research methods and objectives. The results and discussion section is presented thematically and a summary of the main findings is offered in the conclusion.

## 6.1 Introduction

The purpose of the research collaboration was to create and evaluate a mobile app for practitioners involved in blood transfusion. It is an attempt to intervene to reduce mistakes in the use of irradiated and CMV-negative blood components. As with the all action research projects, the project must be guided by an accurate understanding of the problem. This requires identifying the stakeholders and soliciting their understanding of the problem and their views it to address it.

As discussed in chapter three, failures to provide special blood components according to guidelines is a challenge that requires several interventions and collaboration across disciplines. Additionally, [Checkland and Poulter \(2010\)](#) argue that different stakeholders may approach a problem in multiple ways based on their view of the world ('weltanschauung'). It is thus essential to engage with a range of actors and approach the project in an open and collaborative manner.

With these considerations in mind, this study aimed to test my assumptions, which were predominantly based on published haemovigilance data. I also hoped to gauge to what extent an app could be an acceptable approach and sought to solicit early practitioner feedback on the initial working prototype (shown in figure [6.1](#)). Before proceeding, I will briefly describe the version of the SBC app used in the study.

### 6.1.1 Initial SBC prototype

As discussed in the methodology chapter, the Special Blood Components (SBC) app was iteratively developed, using an approach inspired by action research, co-design and agile software development. This meant that the app underwent several re-designs based on feedback from healthcare practitioners. This chapter reports on the initial prototype.

The first version of the SBC app was conceived of as a cognitive aid and simple decision support tool covering difficult to remember indications of blood transfusion (some of which were discussed in chapter three). It was intended primarily for doctors involved in prescribing blood transfusions.

The scope included not just irradiated and CMV-negative blood components, but also haemoglobinopathies, such as sickle-cell and thalassemia, transfusions in patients with clinically significant antibodies, use of emergency blood, massive haemorrhage transfusions and recommendations for Rhesus-D negative women of childbearing age at risk of haemolytic disease of the newborn. Thus, this early version contained clinical indications for a broad range of special transfusion requirements (fig. 6.2). It also featured a simple knowledge quiz (fig. 6.3).



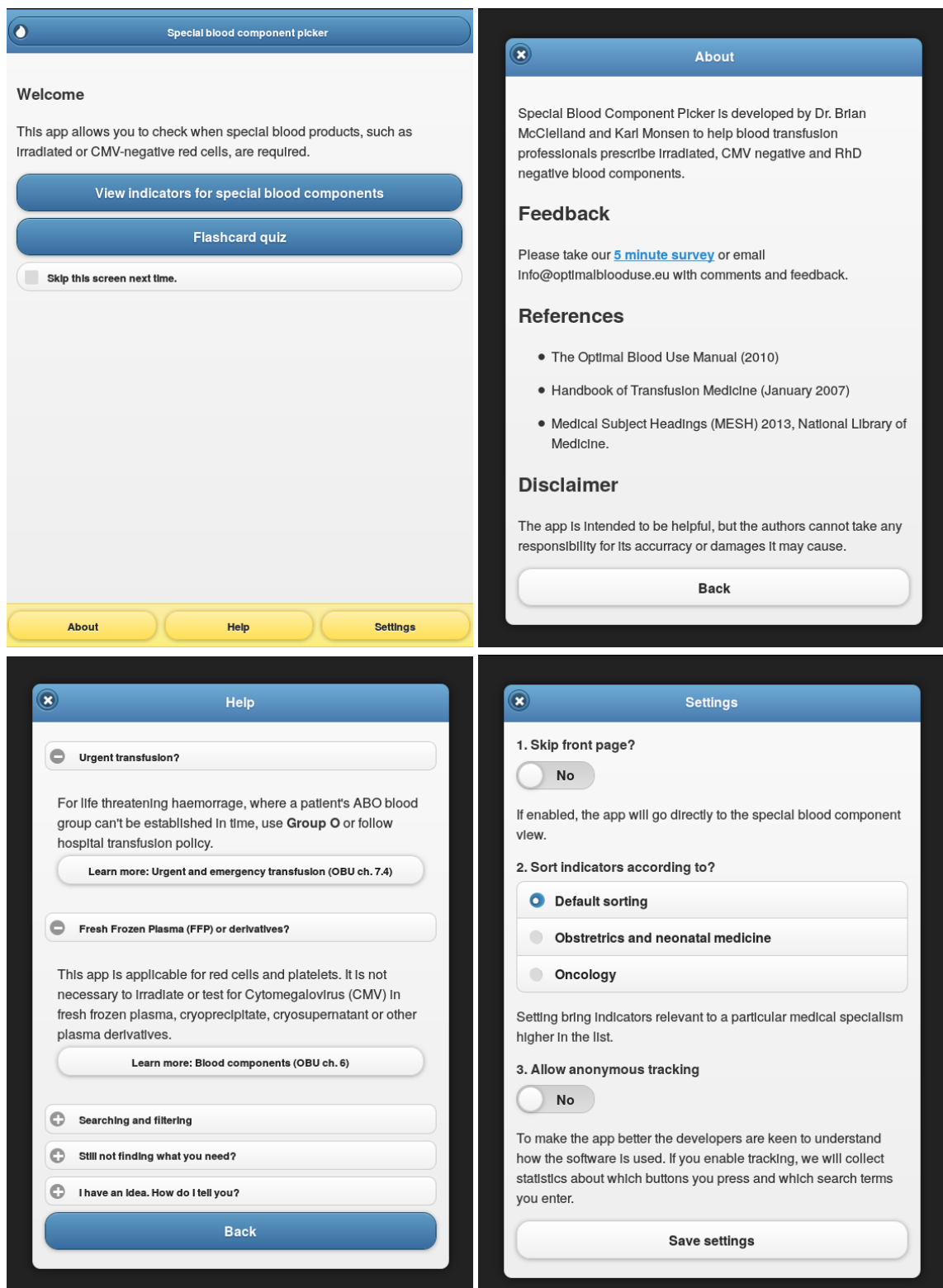


Figure 6.1: Welcome screen and associated dialogues in the Special Blood Components prototype. Clockwise: main screen; about page; help page; and the settings page.

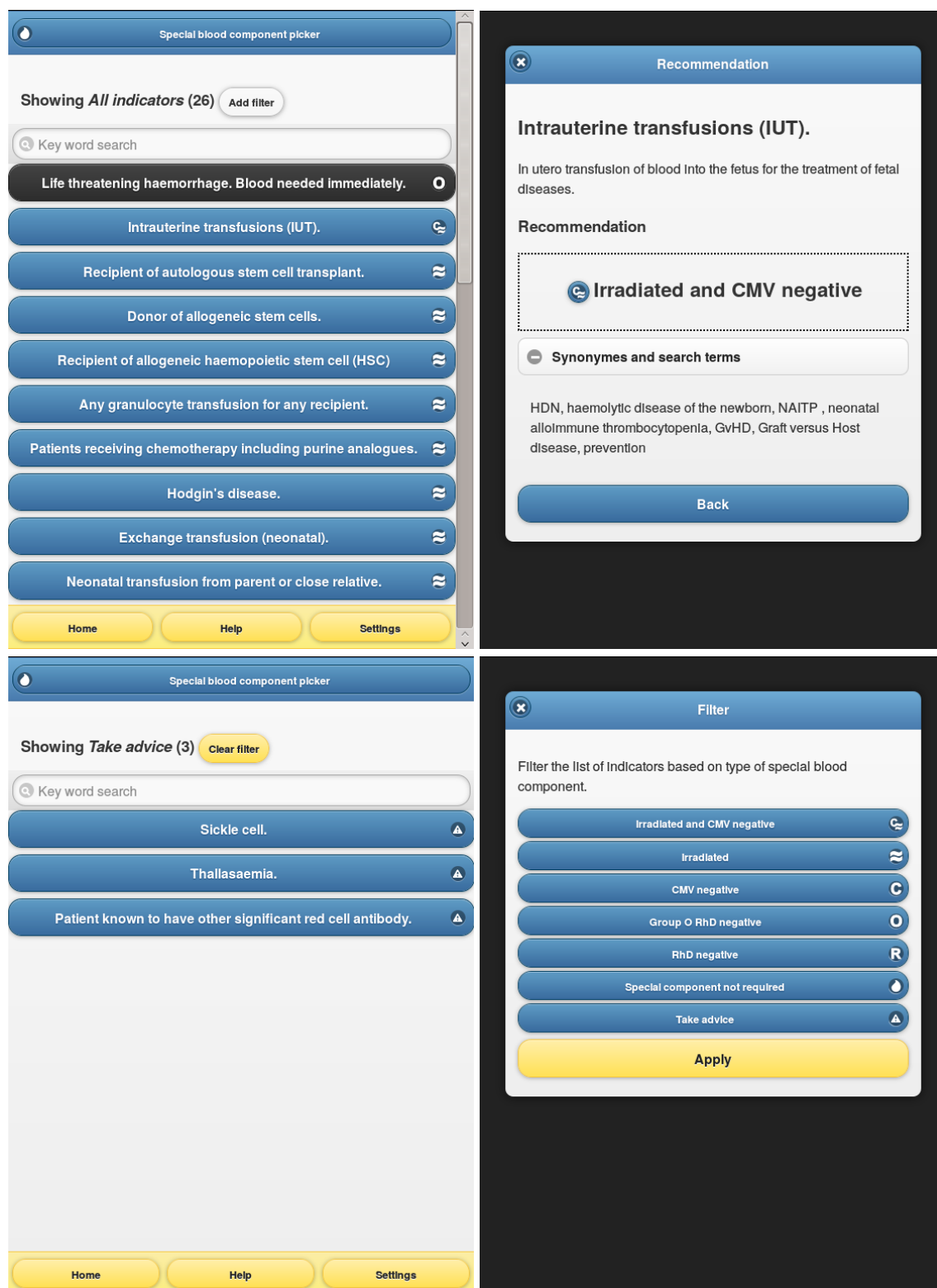


Figure 6.2: Indications section of the Special Blood Components prototype. Clockwise: the complete list of indications; detailed view of the recommendations for intrauterine transfusions; options for filtering the list of indications; subset of the indications list, showing only items for which taking advice is recommended.

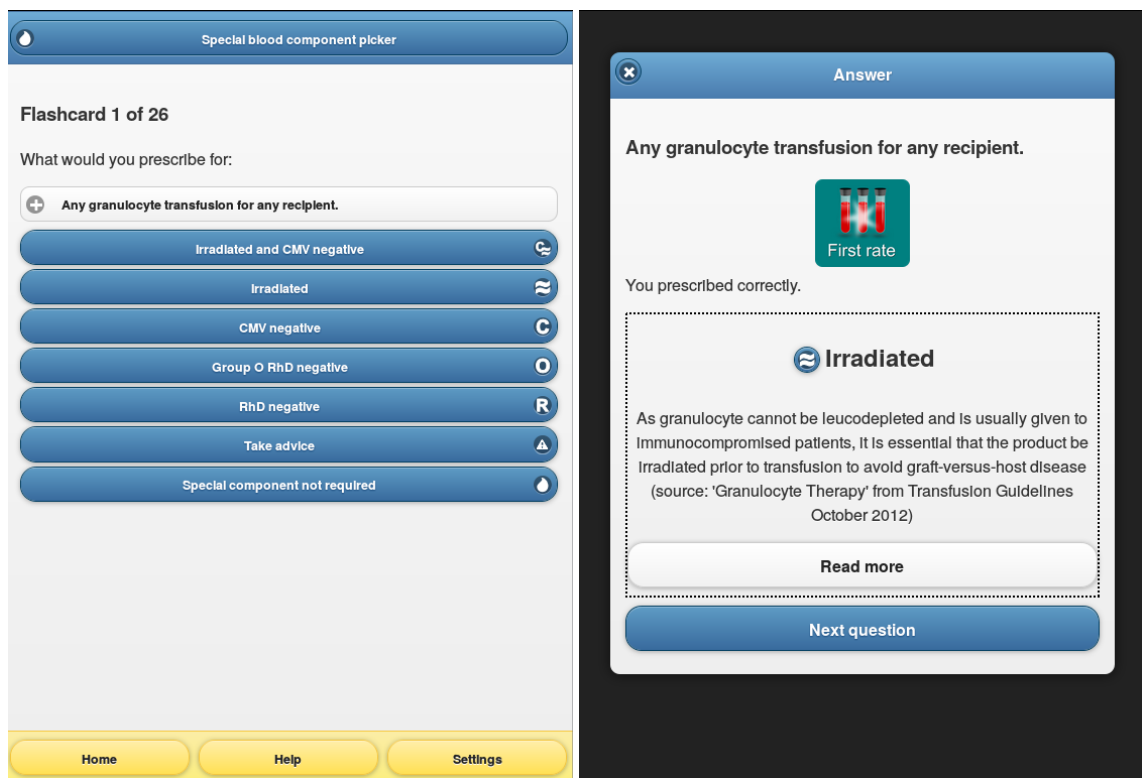


Figure 6.3: Quiz section of the Special Blood Components prototype, showing an example question and feedback dialogue for selecting the correct answer.

## 6.2 Methods

This study was conducted in a similar manner to the review of the Platelets app, which was discussed in the previous chapter. That is to say, it involved the same research participants and they were interviewed using the same process (see schedule in appendix A.2). There were four semi-structured interviews (Gillham, 2005) with three haematologists (one consultant and two registrars), three anaesthetist consultants and one transfusion practitioner nurse. Participants' professional roles, approximate age range

and “thumbnail technobiography” is summarised in the previous chapter (table 5.1).

The interviewees were recruited through the Scottish National Blood Transfusion Service (SNBTS) and were self-selected. Two of the interviews were group interviews, with two and three participants respectively. The remaining were single interviews. The length of the interviews varied between one and two hours.

Participants were encouraged to freely explore the prototype and to think aloud during the interviews to help identify usability problems (Holzinger, 2005, 73). The interviews were recorded, transcribed, coded and analysed by hand, loosely following a grounded theory approach (Glaser and Strauss, 1967; Strauss and Corbin, 1998). The findings were organised into the themes summarised in table 6.1.

Table 6.1: Themes identified in the interviews.

Theme	Aspects covered
Problem definition	Extent, reasons and severity of problem; existing local solutions and limitations in these; perceived possible solutions.
Appropriateness of an app	Questions about scope, audience and purpose of the app; app as a learning aid; familiarity and acceptability of using apps; likely limitations of an app.
Collaboration	How and who to collaborate with; ways of evaluating and disseminating the app;
Contents	What indications to include; what sources to draw on; what search terms to include; discussion of scientific evidence.
Usability	Presentation of information; use of language; possible decision algorithms; visual design; familiarity.

After the interviews, the clinicians who I interviewed, and three additional collaborators with blood transfusion backgrounds, were emailed an invitation to preview and comment on the revised app. The email contained a brief progress update and instructions for how to leave feedback (see appendix A.3 for a copy of the email invitation).

All follow-up feedback data was captured remotely via email, phone or the online survey. In addition, the app contained integration with Google Analytics, enabling tracking and analysis of how users accessed the app. The app's terms of use, presented to the user when opening the app, explained which data was collected and why. The feedback questionnaire included information about the research aims and conditions for participation. A copy of the questionnaire is provided in appendix C.3. Participants also helped pilot the questionnaire, which would later be used for an evaluation of the app with final year medical students – the topic of chapter eight.

## 6.3 Results

The interviews confirmed the incidence of mistakes in the use of irradiated and CMV-negative blood. The haematologists that I spoke to gave several examples where non-irradiated blood had incorrectly been transfused to patients with special requirements:

“We’ve had errors which we have reported to SHOT [Serious Hazards of Transfusion]. We had a child who was harvested [for stem cells] and got non-irradiated.”  
(Jane, consultant haematologist)

In another case, failure was caused by incomplete handover of information when a haematology patient received care at another hospital that used a different IT systems:

“One of the haematology patients from here had to have a transfusion at a different hospital, and that information wasn’t on their system. I think [the patient] actually got non-irradiated red cells. That was flagged up as an [–] incident in the system.” (Sarah, Haematology Registrar)

Sometimes, special components were also requested inappropriately:

“We’ve had a case where a sick kid was requested irradiated, when they didn’t need it. The reason they requested irradiated was because this patient was pancytopenic [deficient in all blood cell types] from leukaemia therapy. So, it is in a way equally important to identify [situations that] doesn’t need irradiated. In this case, it depends on the type of chemo or underlying diagnosis.” (Jane)

Unnecessary requests for irradiated blood components could harm patients in time-critical scenarios. Knowing when irradiated blood is not required can avoid delay:

“I can tell you of someone who requested irradiated when they didn’t need it. It was in a [...] major haemorrhage situation, and it got them tied up in knots. And despite explaining it 24 hours later, I was having the same discussion with them again.” (Jane)

These examples illustrate failures to request and to communicate special requirements during shared care, as well as the inappropriate request for special blood components in situations which could be time-critical. Considered together, these examples confirm the case reports published by SHOT and provide first hand accounts of the types of mistakes, causes and impacts they have on patients and practitioners.

### 6.3.1 Systems for managing special requirements

Ensuring that patients with special requirements are identified and always given the correct blood component is challenging. This issue led to the introduction of a formal process in one of the hospitals whereby the blood bank is notified of any patients with special requirements:

“For the very same reason that you have been thinking about this app – there had been quite a few near misses if you’d like where all non-irradiated products were requested, and it was only picked up by the lab – we’ve actually changed the system within the haematology department.

So, when a patient is newly diagnosed – and that’s a consultant decision – a form goes down to the haematology lab so that it is documented on the blood transfusion lab system. So we as juniors are not required to tick any boxes, and it is given that the information is already down in the lab.

It is really up to the senior team, so the consultants, if they are giving a new drug, such as fludarabine or whatever. And if that changes then that information has to go down in a new form. [–] That form is then filed with the patient’s notes.”  
(Sarah, Haematology Registrar)

As the haematologist registrar explained that there have been near misses, where mistakes were detected and prevented before patients were affected. This led to the introduction of the special requirements notification system. A similar system was introduced for the same reasons in the hospital where Jane is haematology consultant:

“[The use of irradiated blood components] is such a problem, and they get it wrong so often, that we actually have a system where, if a patient is identified as requiring irradiated products, the blood bank is informed. And we put that on [...] our IT system for SNBTS [Scottish National Blood Transfusion Service]. So that any time that a patient comes through an SNBTS blood bank, nobody needs to think about it. [...] That’s how bad this is.” (Jane, consultant haematologist)

While Sarah felt that the system had worked well in her department, Jane explained that their system have potential to lead to a false sense of security because it was being perceived as fail-safe. Jane highlighted the danger, using an example of a consultant who suggested it was unnecessary to always complete the special requirements on the blood request form as the system would catch errors involving special requirements:

“My understanding is that it is the consultant who proposed [...] that you don’t actually have to request irradiation every time because they know that there is a fail-safe system. [—] I think this is wrong. They should always request irradiated because if there is a visitor from England it falls through.” (Jane)

“Or if the IT system is down, like ours was the other day.” (Laura, transfusion practitioner)

These views are echoed in a SHOT recommendation based on a case where a pregnant woman was not provided with CMV-negative blood for an elective operation. This incident was caused by a failure to complete the request form fully and SHOT recommends that : “It must never be assumed that the laboratory staff will know what the patient’s requirements are and they should be confirmed by selecting the appropriate option on every request form.” (Bolton-Maggs et al., 2015a, 61).

SHOT have also highlighted that failures to provide special blood components can happen because of missing, incorrect or ignored flags in the hospital or blood bank information systems (Bolton-Maggs et al., 2015a, 62), adding to Jane’s point that these systems are not fail-safe.

The transfusion practitioner commented that it was some time since an incident was raised in the system for detecting mistakes, suggesting either that practice has



improved or perhaps that the system is not detecting mistakes:

“There used to be an incident if it flagged up on [the laboratory IT system] and [...] I’ve not had [a notification of an incident] for long time.” (Laura, Transfusion practitioner)

One of the haematologists had a different explanation. She explained that there is likely to be under-reporting since mistakes can go unnoticed due lacking awareness:

“It is only those who realises they have made a mistake and comes back to us that we can pick up.” (Jane)

### 6.3.2 Causes of mistakes

Over the last ten years, the SHOT reports have identified several causes of mistakes involving irradiated and CMV-negative blood components, including a lack of clinician knowledge, inadequate communication during shared patient care and IT system failures. The interviews confirmed many of these findings. For example, Jane felt that there was a poor level of knowledge for some of the indications for irradiated blood:

“[Clinicians] keep falling down on [Campath and ATG] [–] [They are] not necessarily making the connection that they need to be using irradiated products.” (Jane, consultant haematologist)

James, one of the anaesthetists, also felt that there was limited knowledge of the indications, as well as a general the lack of awareness of the rationale for using special blood components:

“Obviously there is a difficulty of remembering what [the indications for irradiated and CMV-negative blood components] are. But I think the common problem is that [clinicians] won’t even think about it. Patients come into ITU [intensive treatment unit] who have previously been at an other hospital, and that there is an indication for special requirements doesn’t cross anybody’s mind.” (James, consultant anaesthetist)

He went on to compare this issue with the challenges related to implementing medical guidelines – such as promoting their use and changing medical practice:

“One of the big problems that we have with guidelines – and I guess it will be the same for the app – is not that people don’t follow them, but that they don’t know of their existence. They don’t get to the stage of even looking at them. By the time they think ‘maybe this patient has a special requirement’, you’re almost there. You just need a little bit of help to clarify it. It is not having realised it, that is the issue.” (James)

Furthermore, Andrew commented that checking whether a patient has special requirements is a low priority for most clinicians:

“The fact that a patient needs irradiated blood is low on the list of priorities of things that anybody has to remember when they see almost any patient. It just happens to be very important if you get it wrong. We know its an area where lots of mistakes are made. We got plenty of evidence for that.” (Andrew, medical adviser to project)

Disparate IT systems between hospitals and departments is another reason for why mistakes can happen. One of the haematologists explained how this situation prevents information from being automatically shared between caregivers:

“Unfortunately, the computer system here is not directly linked to other hospitals [...] The plan was to have those [irradiated blood] forms communicated to other hospitals, so it would be on the same system. But it has to be done on an individual

basis, and sent through as a purposeful act, rather than it automatically getting linked up. So there is always room for error, unfortunately.” (Sarah, haematology registrar)

The national guidelines for irradiated blood recommends that patients should be given a card stating that they require irradiated blood and instructed to show the card to healthcare staff (Treleaven et al., 2010). However, Sarah felt that patients cannot be relied upon to communicate their special requirements and that linking up IT systems would improve safety:

“The link up of different labs is important for some of the patients. For those with Hodgkin’s [lymphoma] it’s a life-long [condition], and for the stem-cell [therapy patients] it is becoming a life-long period. [—] I suppose Hodgkin’s [patients] do so well so they forget they’ve had it twenty years ago, and they don’t mention it.” (Sarah)

### 6.3.3 Professional knowledge boundaries

Assessing if a patient should receive irradiated and/or CMV-negative blood components require detailed knowledge of the clinical indications. Unless one sees patients with special requirements on a regular basis, making the correct decision can be hard:

“It is [a complex decision] if you are not a haematologist. It is bread and butter for us, but it is [a complex decision] if you are not a haematologist, yes.” (Jane, haematologist consultant)

This view was mirrored in a comment by David who felt that the clinical indications are mostly irrelevant to the majority of doctors - until they encounter a patient where it becomes relevant:

“So, what you’ve got here [referring to the SBC app prototype] is a long list of reasons for transfusing [irradiated and/or CMV-negative] blood products, most of them fairly rare. Because most transfusions are going to be red cell transfusions for non-haematology patients for anaemia or bleeding [—] for most doctors, most of this is not relevant. [...] it is the one specialised patient that comes into a general ward with another problem that is the highest risk. If it is a specialist ward, then it’s fine. Everybody knows.” (David, consultant anaesthetist)

Non-haematologists do of course prescribe, request and administer blood components to patients with special requirements occasionally. This is the reason that SHOT recommends that “The existence [...] of special transfusion requirements must be taught to junior doctors in all hospital specialities.” (Cohen et al., 2010, 55). However, Jane felt that the SBC app should not only target junior doctors:

“I would not just aim this at junior doctors. We have many senior consultants who have genuinely said: “Do I need irradiated products?” (Jane, consultant haematologist)

“Right. I’m not surprised to hear that.” (Andrew, medical adviser to project)

“But these are people who I personally would have expected them to know.” (Jane)

“Would they use something like this, do you think?” (Andrew)

“I don’t know.” (Jane)

“Their registrars might.” (Mary, haematology registrar)

“Yes, but the mistakes were made by consultants. If they’ve made a mistake once, they know to go back and check next time.” (Jane)

### 6.3.4 Suggestions for improving existing procedures

The anesthetists suggested that having a way of alerting clinicians at the time of requesting blood could be effective since remembering special requirements is difficult:

“The other point, which you touched on, is that if people think of using the app, then they will have thought through already, maybe this patients needs irradiated.” (Andrew, medical adviser to project)

“Yes, so you are halfway there. You’ve already got the red flag waving. Something is out of the ordinary here. And actually that is half the battle. What we are trying to avoid here is somebody saying: ‘Oh I just give them a couple of red cells’ without thinking. Which is very easy to do.” (David, consultant anaesthetist)

An idea that came up repeatedly was incorporating decision support prompts at the time of prescribing blood components. This has been explored by [Turner et al. \(2003\)](#) who evaluated a handheld bar code scanner with built-in prompts. They found that prompts improved adherence to special requirements checking. A similar approach has since been incorporated into an end-to-end system electronic transfusion management system ([Murphy et al., 2012](#)). However, such a system was not implemented in any of the hospitals included in this study and no prompts related to special requirements were in place:

“If you put in an x-ray, you get a prompt saying might the patient be pregnant [...] but blood transfusion has been avoided from being incorporated into that system. [...] At the moment it is difficult to impose a sort of question every time anyone requests a blood transfusion.” (David)

“We are a bit atypical. The majority of hospitals are in a position to do that. I don’t know how many have done it. It is something we should explore. Because the blood bank data is handled through the main laboratory system, which is not the case here, they have the facility to put all kinds of haematology alerts on there, if they want to.” (Andrew)

### 6.3.5 Improvements to the SBC prototype

The interviews also identified areas of improvement in the Special Blood Components app prototype (summarised in table 6.2). When addressing these points, it was difficult to find a good way to feed changes back to the research participants. For example, sending a spreadsheet was a clunky way of collaborating on changes to the app:

“...what would be the best way to provide the new text to anybody who would be prepared to look through it and make some edits. Would you send the app and say give us notes with anything that needs to be changed? Or how would you handle that?” (Andrew)

“The database behind it is basically a spreadsheet. So that might be the easiest way; to circulate a spreadsheet. [—] [but] it would be hard for you to see the differences if I just sent you the next version. It would be good to set up some kind of editorial system. I’m not sure how to do that at the moment.” (Karl)

After investigating this problem further, it became clear that there were few suitable tools for easily sharing changes to the app with collaborators.

## 6.4 Discussion

The interviews provided perspectives on why the correct use of special blood components is challenging, and how it could be improved. For example, the haematologists who regularly worked with patients with special requirements, were able to give examples of when and why incidents occurred, and how these were managed.

They emphasised the importance of having robust systems for capturing and communication special requirements, and for raising knowledge of the issue among prac-

tioners in other specialties, including at consultant level. The view was shared by the transfusion practitioner nurse who was responsible for improving the local hospital transfusion process by monitoring transfusion incidents and training staff. These comments strongly reflect the key recommendations provided in the reports by SHOT.

The anaesthetists provided another angle on the problem. Unlike the haematologists, they rarely knowingly encounter patients with special requirements, were less familiar with the topic and somewhat hesitant to admit gaps in their knowledge.

Table 6.2: Areas of improvement for the Special Blood Component app.

Area of improvement	Required action
Score, audience and purpose	Limit scope to irradiated and CMV-negative blood. Remove haemorrhage, emergency blood, RhD-D negative blood components, sickle cell disease, thallasaemia and significant antibodies.
Content	Update indications for CMV-negative components according to the guidance from SaBTO. Ensure that the indications follow the national guidelines to the letter. Improve taxonomy of search terms by adding common misspellings, relevant clinical diagnoses and the names of increasingly used chemotherapy drugs (e.g. Campath/Alemtuzumab). Add a section that explains the rationale for the use of irradiated and CMV-negative blood components. Expand the use of references and rely directly on the national guidelines instead of secondary sources.
Features	The list of indications is quite long. Re-investigate the feasibility of adding a decision support algorithm to make it faster and easier to check if there are any indications that might apply to a given situation.
Usability	Make the search feature for the indications more prominent. Improve the icons as their meaning was not intuitive. Use colour-coding, possibly based on a traffic lights system, to make the indications easier to scan. Group and prioritise the indications list carefully, perhaps by specialty or frequency.

However, they agreed it was a challenging topic, and that poor awareness of the indications for special blood components was an important cause of the problem. They also felt that it was hard to remember when irradiated or CMV-negative blood is required, and that special blood components ranked low on their list of priorities.

A recurring comment was that any decision support provided in an app is unlikely to improve the situation because by the time a user opens the app, they were “nearly there”. What was needed was an “externally triggered” reminder, such as a prompt at the point of ordering blood components. This assertion is supported by a systematic review of 20 studies concerning the impact of decision support systems on blood ordering by Hibbs et al. (2015). Although the review did not consider special requirements, they found good evidence that such systems promote appropriate use of red cells. However, this did not exist in the hospital involved in this study because the blood ordering system, which was separate from the main hospital information system, lacked support for decision support prompts.

Their comments encouraged me to think more broadly about the problem and the purpose of the app. As well as offering easy access to the indications, it could function as a learning aid to raise awareness of the problem. There are SHOT cases illustrating the importance of wider awareness of the issue among nurses and patients, as they have prevented mistakes made by clinicians. It could increase the likelihood that mistakes could be picked up at other stages of the clinical transfusion process besides



the prescription of blood components, such as at pre-transfusion checking. It is therefore important to increase general knowledge and awareness of the topic among staff involved in key stages of the blood transfusion process.

## 6.5 Conclusion

In conclusion, interviewing participants from different hospitals, specialties, and with different professional responsibilities and priorities, deepened my understanding of the problem that the SBC app sought to address. This included of the challenges of providing continuity of care given variations in information systems and processes between hospitals. A limitation of this study was that it only captured the views of a small number of practitioners.

However, it was large enough to observe differences and similarities in how the participants defined and analysed the problem, and how they identified potential solutions. This early input from clinicians was essential for developing a better understanding of the problem from multiple viewpoints, for identifying inaccuracies in the app's data model, for improving the usability, and most importantly for refining the purpose and audience of the app. It also became apparent that it an issue that requires more than one interventions to tackle.

Finally, the comments offered by participants helped to improve the SBC prototype and convinced me that it was worth continuing its development. I did, however, en-

counter difficulties in effectively sharing work in progress with participants to verify I had corrected the issues that they had identified. This difficulty prompted the third study, where I create and demonstrate a collaborative app editor. The Web App Editor would become a vital tool for sharing work.

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# Chapter 7:

## Study 3: Collaborative App Design with the WAE

This chapter shifts focus from the blood transfusion domain to the software engineering and collaboration processes involved in the development of mobile apps. It discusses the design and testing of the Web App Editor (WAE), a web-based tool designed to make it easier to collaboratively develop apps.

The first part of the chapter draws on data collected during two courses in mobile app development where the WAE was used. It builds on work previously reported in [Monsen \(2013\)](#). The second part is based on an interview with a Master student who used the WAE to develop an app for stroke patients. This work is the basis for [Mamalaki et al. \(forthcoming\)](#).

## 7.1 Introduction

Carayon and Wood (2010) argue that healthcare practitioners, human factors experts and systems engineers must collaborate and learn from each other in order to improve patient safety. As I discussed in chapter two, interdisciplinary collaboration is also critical to create high quality medical apps that are supported by evidence. For instance, Car et al. (2008, xxvii) argue that there is a need for “... a methodological toolkit to facilitate evaluation of eHealth applications throughout all aspects of the development and deployment life cycle of these technologies”. Similarly, von Hippel (2001) demonstrates how “user innovation toolkits”, including computer aided design software applications, have lead to new products in many sectors.

I observed at the end of chapter six that there is a lack of collaborative tools for co-designing medical web apps. For example, resorting to emailing spreadsheets to collaborators is not conducive to agile and iterative app development. The objective of this study was thus to create a collaborative authoring tool to facilitate effective participative app design and explore its usefulness beyond the context of the SBC app. It sought to explore to what extent and how the Web App Editor (WAE) could enable novice app developers to create mobile apps. Before describing the study methods, I will elaborate the background to why and how I created the editor, and how it compares to prior art.

### 7.1.1 Origin as a constructivist learning tool

As was mentioned in chapter two, digital literacy is important to allow users to become involved in the medical app development process. An obvious method for improving digital literacy is to teach app development to learners who are interested in this topic, but unfamiliar with software development.

The precursor to the WAE was created for the delivery of a course on app development for beginners that I first taught in 2013. It aimed to explain how HTML5 apps work and encourage beginners to learn to create apps through examples. Consequently, I created a very simple code editor that could load and modify code templates (table 7.1). These were designed to separate the content from the logic to enable learners to change to the content without having to make extensive changes to the code, although students were encouraged to experiment to support deeper learning.

This pedagogical approach was inspired by the constructivist approach to teaching programming concepts to beginners, pioneered by Papert et al. (1979). Their seminal work on the Logo programming language has since inspired beginner-friendly visual programming environments, including Scratch (Resnick et al., 2009), Catroid (e.g. Slany, 2012) and MIT's App Inventor. These have enabled a diverse range of users to create apps, including children (Slany, 2012), university students outside of computer science (Wolber, 2011), teachers (Liu et al., 2013) and healthcare practitioners (MacKellar, 2012).

Table 7.1: App templates part of the HTML5 app editor environment.

Template	Details
jQuery Mobile multi-page	jQuery Mobile scaffolding necessary to create and link pages within an app.
Geolocative map	Plots the user’s physical location determined using GPS and a custom map layer with user defined points of interest onto a Google map.
JSON data structure	Dynamically creates page content and menus from a JSON (Javascript object notation) data structure using jQuery.
News reader	Downloads and displays a single RSS (really simple syndication) newsfeed.
Battery meter	Shows power consumption based on Firefox’s power API.
Web requests	Creates and handles asynchronous Javascript (AJAX) requests to third party web services.
Physics simulation	Demonstrates the Javascript port of Erin Catto’s <a href="#">Box2D physics engine</a> .

While visual programming environments lower barriers for beginners, they do have some important limitations. The inability to switch easily between graphical code blocks and the source code makes the transition to text-based programming harder. Another drawback of both Catroid and MIT App Inventor is that the resulting apps will only run on Android. More specifically, testing these apps require access to Android hardware, or an emulator that can be slow and frustrating to work with on other processor architectures, such as desktop computers.

In contrast to “native apps”, HTML5 web apps are interpreted or compiled at near run time speed (using just in time compilation), making it is possible to get a near real-

time preview of the app on any device with a recent browser. This can make it faster and easier to debug web apps, which is beneficial for beginners. Indeed, Subhi et al. (2014) argue it can be very easy to create apps using these web technologies and they encourage clinicians to learn how to use them.

Furthermore, there are a number of online services<sup>1</sup> which allow novices to create HTML5 apps by dragging and dropping visual elements. These editing environments are quite easy to use, but restrictive because they are based on predefined designs and lack the ability to change the underlying templates. For example, Masters (2014) discuss how medical students at Sultan Qaboos Univesity, Oman were taught to create medical apps using the iBuildApp web service. The large majority of students favoured a more sophisticated system as they felt constrained by the drag and drop interface (Masters, 2014, 885). Hence, I decided against creating a visual editor for native apps and developed a text-based editor for creating HTML5 apps.

Compared to native development using object-oriented languages such as Java or Objective-C, app development with HTML5 can be an easier route for beginners. There is no requirement for software development kits (SDKs), integrated development environments (IDEs) like Eclipse or Apple's Xcode, or access to specific hardware or emulators for testing.

The interactivity of HTML5 apps is down to Javascript. It is a widely used, but

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<sup>1</sup>e.g. [www.appypie.com](http://www.appypie.com), [www.como.com](http://www.como.com), [www.ibuildapp.com](http://www.ibuildapp.com), [www.appmakr.com](http://www.appmakr.com), last visited 25 June 2015



far from perfect programming language (Crockford, 2008). Compared to native app languages, it could be considered a more suitable language for beginners because it is loosely typed, variables have global scope and the use of object-oriented concepts is optional.

Additionally, web design with Javascript is widely taught as an introductory programming language. For example, Mozilla runs initiatives to teach the basics of HTML to children, such as the School of Webcraft<sup>2</sup> and Thimble Webmaker<sup>3</sup>. Furthermore, Javascript has been used in various online learning settings, including the Khan Academy<sup>4</sup>, Coursera<sup>5</sup> and to teach game programming to children (Strom, 2013). I will now briefly describe the technical architecture of the latest version of the Web App Editor.

### 7.1.2 Technical architecture

The WAE is based on the open source Cloud 9 ACE editor, which allows code to be modified in a web browser. The code editor, together with a live preview of the interpreted code, was initially embedded inside a split-screen layout. Changes were stored locally in the browser cache, using the HTML5 localStorage feature. This allowed coding sessions to be stopped and resumed, but did not provide robust permanent storage.

The updated version of the system, shown in figure 7.1, was modified according to

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<sup>2</sup><https://p2pu.org/en/groups/schools/school-of-webcraft/>, last visited 25 June 2015

<sup>3</sup><https://thimble.webmakwer.org>, last visited 25 June 2015

<sup>4</sup>[www.khanacademy.com](http://www.khanacademy.com), last visited 25 June 2015

<sup>5</sup>[www.coursera.org](http://www.coursera.org), last visited 25 June 2015

student feedback and integrates with the GitHub.com revision control system to allow changes to be saved permanently. A comparison of the features of the different versions of the editor is provided in table 7.4. Furthermore, the editor shares similarities with existing online code editors (table 7.2). The technical architecture of the system is illustrated in figure 7.2. Several freely licensed, open source software components were used to create the WAE, including:

- ACE Editor for editing code, maintained by Cloud 9.
- Share.js for real-time collaborative text editing using the operational transforms algorithm to sync changes, by Joseph Gentle and others.
- Octocat.js Github API javascript library, by Phil Schatz.
- Rawgit for fetching and proxying github files, by Ryan Grove.
- W2UI for the user interface management, by Vitali Malinowski.
- JsTree for managing file structures, by Ivan Bozhanov

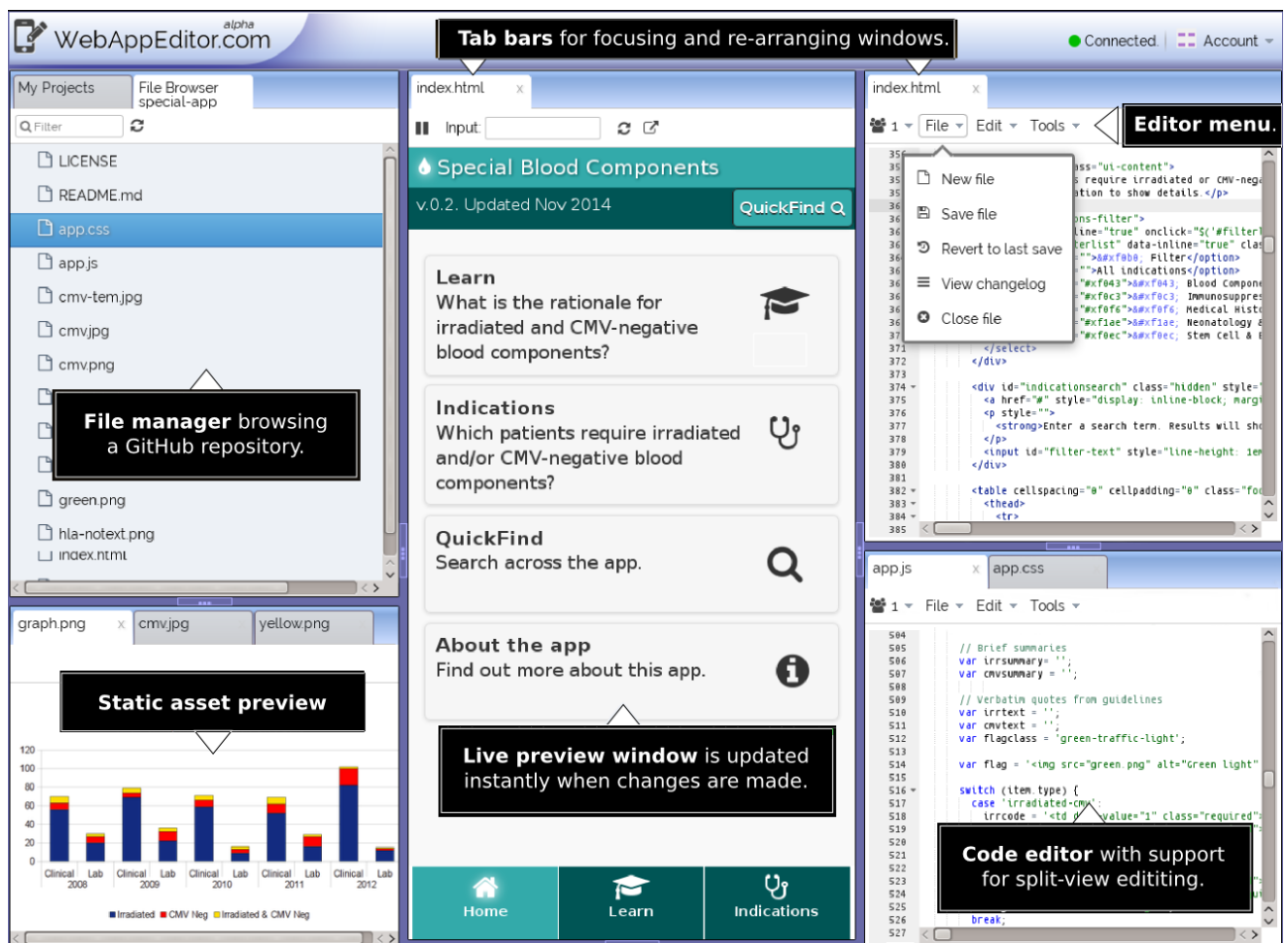


Figure 7.1: Screenshot of the Web App Editor

Table 7.2: Comparison of online collaborative code editors as of March 2016.

	WAE	“Cloud IDEs”		“Prototyping playgrounds”			
		Cloud9	Codio	Codepen	Jsbin	Jsfiddle	Plunker
Code hosting, syntax-checking and preview:	✓	✓	✓	✓	✓	✓	✓
Real-time code editing with multiple authors:	✓	✓	✓	✓ <sup>1</sup>		✓	✓
Live multi-media chat between collaborators:	Text, audio & video	Text		Text <sup>1</sup>		Text & audio <sup>2</sup>	
Advanced file and user interface operations: <sup>3</sup>	✓	✓ <sup>4</sup>	✓ <sup>4</sup>				
Technology stack:	Node	Node	Node	Ruby	Node	PHP(?)	Node
Bundled code editor (CM=Code Mirror):	Ace	Ace	CM	CM	CM	CM	Ace
Source code licensing:	Open	Dual	Closed	Closed	Open	Closed	Open
Price/business model:	n/a	Freemium	Free Trial	Freemium	Freemium	Free	Free

Footnotes:

1. Real-time collaboration requires a premium Codepen account.
2. Text chat and audio conferencing provided through Mozilla’s Together.js library.
3. Operations include file management, version control and changing the editor layout to edit multiple files.
4. Unlike the WAE, version control is only offered via a terminal and require familiarity with the Git command line.

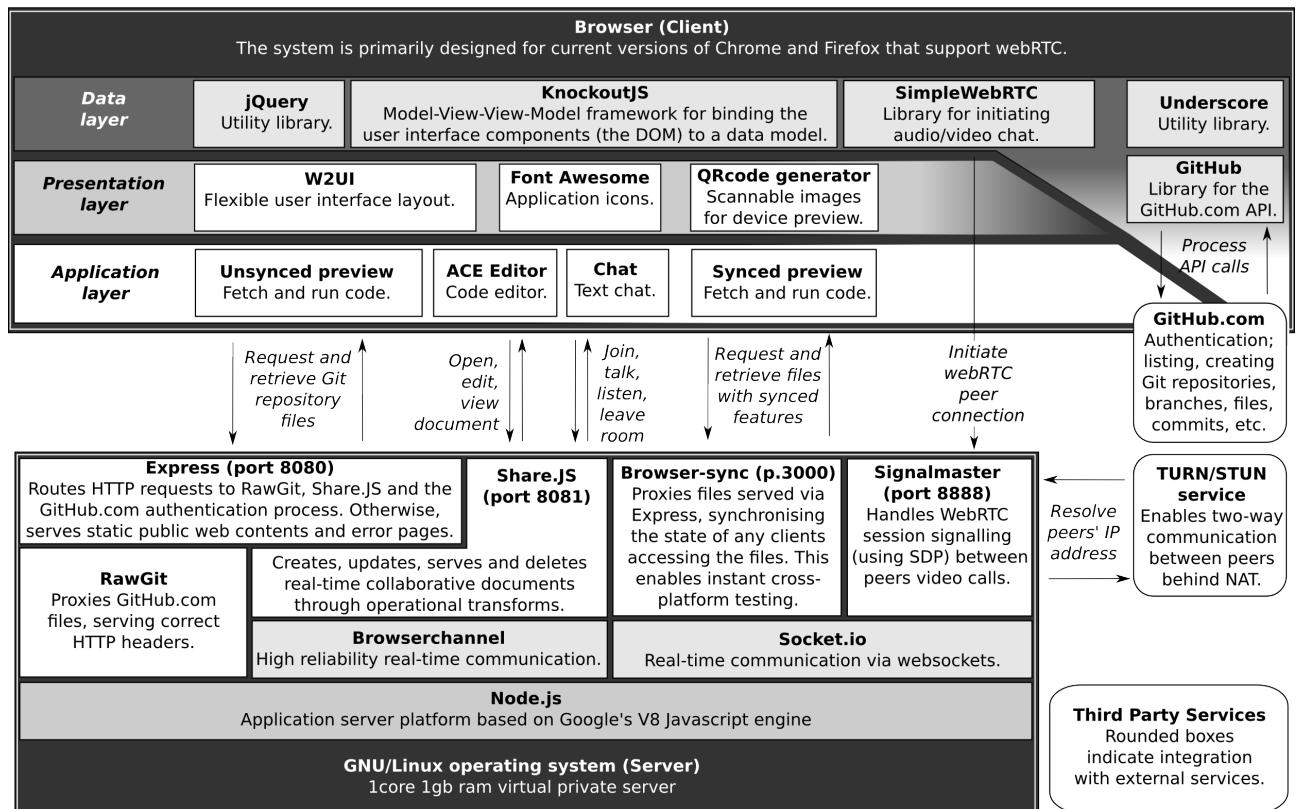


Figure 7.2: Technical architecture of the Web App Editor

Table 7.3: Comparison of the cohorts participating in the study.

	Cohort 1 (2013)	Cohort 2 (2014)
Qualification (unit)	Mobile Technology: Project (SCQF 6).	Mobile Technology: Project (SCQF 6).
Class structure	Evening course: 12 weekly three hour classes.	Intensive course: 1 week with full time classes.
Students in class	8	8
Students surveyed	7	3
WAE version used	v.0.1	v.0.2

## 7.2 Part 1 - Use of the WAE in education

The purpose of this part of study was to examine to what extent and how the WAE facilitated collaboration and digital skills acquisition among users who are new to app development. To examine this, the WAE was evaluated during two certified courses in app development for beginners. I taught the courses, which had a nominal contact time of 36 hours and were offered at higher college level (SCQF 6), approximately one year apart.

### 7.2.1 Methods

At the end of each course, students were invited to participate in an short online questionnaire about the use of the WAE in the course (see appendix B.1). The questions explored students' prior experience of installing, using and creating apps. It also asked them to comment on and rate the editor using the System Usability Scale (Brooke, 1996). However, it was not answered by a sufficient number to merit analysis.

Because the number of respondents are small, the results from both classes will be discussed together. Although both cohorts attended the same course, there were some differences (see table 7.3). Most notably the WAE was under heavy development during the courses. The first cohort used the initial prototype version that had a much smaller feature set (see table 7.4). Cohort two used a more fully-featured version, also incorporating feedback and bug fixes, identified in part by students in the first cohort.

Table 7.4: Key features of the WAE by version.

	WAE v.0.3 (2015)	WAE v.0.2 (2014)	WAE v.0.1 (2013)
<i>Storage and file management</i>			
Temporary file storage (localStorage).	-	-	✓
Permanent storage with version control (GitHub.com integration).	✓	✓	-
File handling (uploads, renaming, etc).	✓	✓	-
<i>Development and testing</i>			
Syntax highlighting and checking.	✓	✓	✓
Project hosting and instant preview.	✓	✓	✓
Split-screen editing	✓	✓	-
<i>Collaboration</i>			
Real-time pair programming (ShareJS).	✓	✓	-
Text, audio and video chat (WebRTC).	-	✓	-
Collaborator activity feed (Github).	-	✓	-
<i>Preferences and customisation</i>			
Editor theme and font options.	-	✓	-
Flexible, tab-based user interface.	✓	-	-

The objectives of the course was to give students an opportunity to plan, create and evaluate a mobile app. There were no course prerequisites and to bring everyone up to speed the first four sessions were dedicated to HTML, Javascript and jQuery Mobile - a library for creating mobile web applications.

Prior to collecting any data, participants were informed about the purpose of the research and how their answers would be used. Their responses are reported anonymously. Permission was also obtained to present sample student work.

### 7.2.2 Results

Nineteen students enrolled in the courses, but three withdrew early for different reasons. This left sixteen students, of which ten - six women and four men - agreed to participate in the study. Two students were 24 or younger, two were between 25 and 34, two were between 35 and 44, and the remaining were 55 or older.

#### Background of participants

Students were confident mobile phone users and a majority reported using apps on a regular basis (fig. 7.3). For instance, one student claimed that their phone is “always on and always getting used” (female, 35-44). Another felt that “apps have become part of everyday life, however, I only use a handful of the many that I download” (male, 25-34).

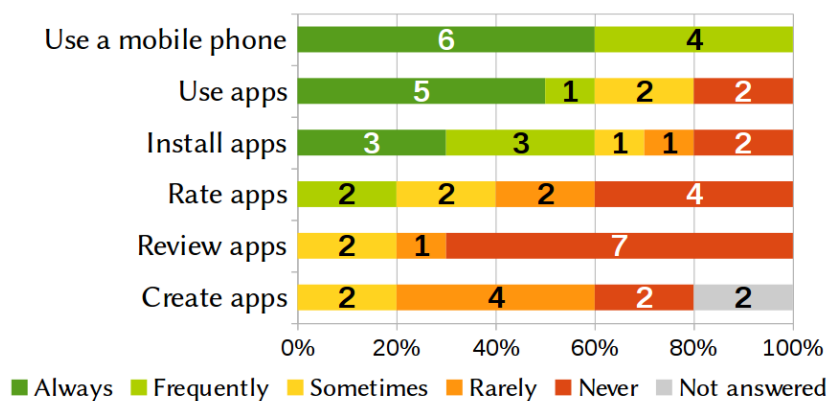


Figure 7.3: Prior experience of mobile technology among the students.



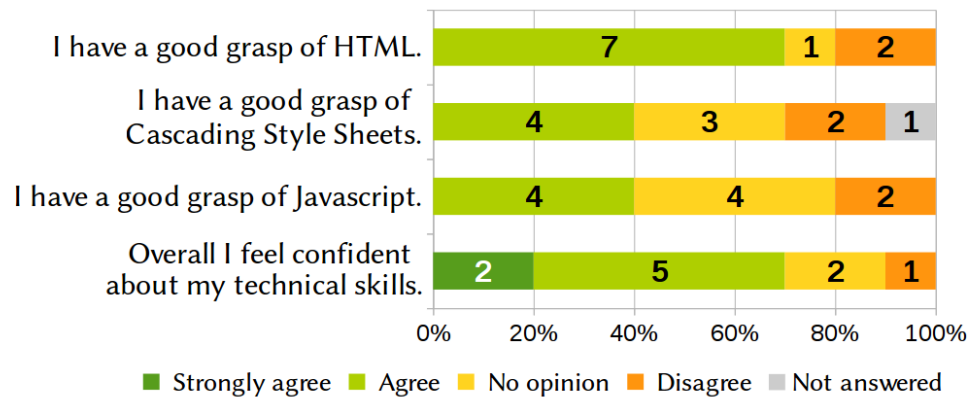


Figure 7.4: Confidence in technical web design skills at the end of the courses.

That said, it is important to emphasise that not everyone who participated in the course used apps or had significant smartphone experience. For example, one participant reported: “I personally do not download extra programmes onto my telephone” (female, 55-64). Although one third of students indicated that they sometimes rate apps in the app stores, only one person had prior experience of creating them:

“I regularly update, remove and install apps. As I am interested in computer development as a whole I have made a few apps, though I cannot say I have great experience of the subject.” (male, 24 and under)

When asked to evaluate their own skills at the end of the course, many participants indicated that they have a good grasp of web technologies (fig. 7.4). However, several students also acknowledged that they still have much to learn:

“Whilst the fundamentals of HTML and CSS are there, I strive to learn as much as possible to improve skills. With more browsers adopting modern standards, the use of HTML5, CSS3 and Javascript to create quality user experiences is becoming the norm. I would appreciate any opportunity to enhance my knowledge of Javascript.” (male, 25-34)

Furthermore some students had not done much web development before: “It was the first time I used a lot of Javascript and HTML” (male, 65 and over). When asked if the approach of the course could encourage more people to develop apps, one participant argued that the lack of course prerequisites was important in achieving this:

“The approach of the course was very inclusive and assumed no prior knowledge, I think this would encourage people who would otherwise feel alienated by technology to ‘give it a go’ ” (male, under 24)

This is supported up by a statement made by another student who had little initial confidence about using apps: “I knew very little about apps when I started the course. I would feel more confident about using them in future” (female 55-64). Of the more advanced students, two had professional web design experience and were able to create more sophisticated apps. They also often shared their skills with the rest of the class. Although the diverse range technical experience of the class made it hard to meet each learners’ individual needs, one student saw this diversity as something valuable, perhaps due to the sharing of skills between peers:

“I think the class was a mixture of people who had a lot of experience with apps and others who had very little experience. It is certainly a good mixture of backgrounds which is to be commended.” (female, 55-64)

### **Effectiveness of the development environment**

When asked to rate the development environment and code examples, most students agreed that it was easy to create apps using this approach, especially for changing

content (fig. 7.5). Modifying the structure of the app, such as creating new pages, was felt to be harder and only five out of seven agreed or strongly agreed it was easy. Notably, a majority of participants did not agree that modifying the core functionality of the app was easy. Given that most students lacked strong programming skills at the start of the course, this was not unexpected. For example, one of the students felt that understanding the code was challenging, and would have liked more time to learn programming:

“The technical language is difficult and not easy to decipher. Once I saw the pattern of the code it was easier to input my own. [...] I think the course should be longer to give time to practice.” (female, 55-64)

However, another student felt that with adequate support, coding became easy: “I find coding easy once you are shown how to do it” (female, 35-44). Coupled with the sample code and teaching support, the development environment was perceived as a useful way of editing code:

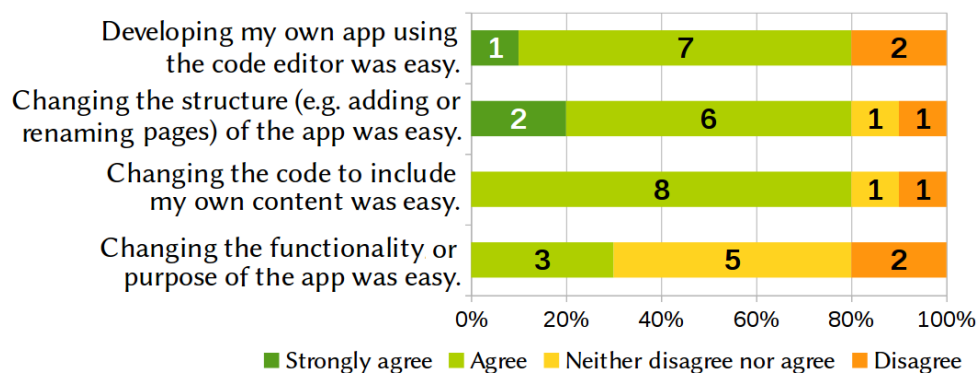


Figure 7.5: Participants' experience of using the Web App Editor (WAE).

“The code examples provided were very useful, as was the input of the course tutor who helped with steering the code in the direction of the functionality you were looking to achieve. The editor helped with real time changes. ” (male, 25-34)

Although one student also used another editor, which he was already familiar with, he agreed that the Web App Editor was easy to use, and the live preview particularly so:

“I used my own text editor (Sublime Text 2) for most of the work I did during the course. However, when I did use the online code editor it was simple and easy to use, especially the live demo. ” (male, 24 and under)

In terms of improvements, one student suggested that integration with a revision control system, such as GitHub, would be advantageous for storing and reviewing code changes.:

“GitHub would help us to make the app more effectively, roll back changes, even enable collaboration, but most importantly, introduce the user to a valuable tool and resource for the future.” (female, 55-64)

This feature was subsequently added to the editor. I will now describe some of the apps that the students created using the WAE during the courses.

### **Resulting apps**

All students succeeded in creating apps, suggesting that the course and development environment was effective for people new to app development. Figure 7.6 shows screen captures from a selection of the diverse range of apps that were completed.

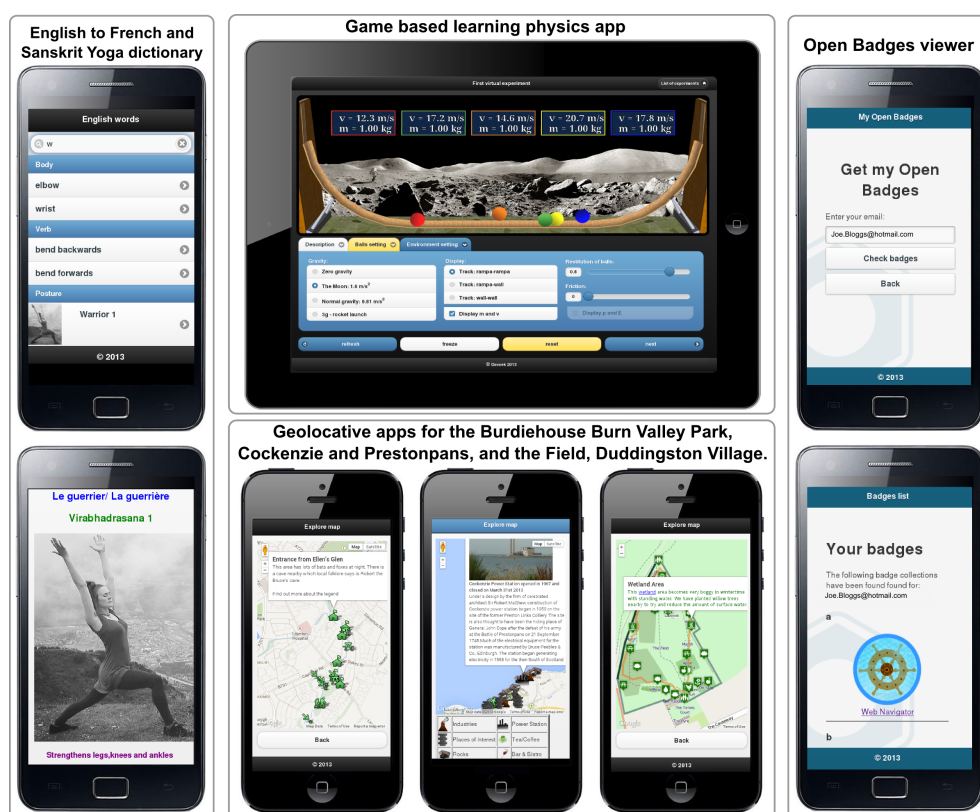


Figure 7.6: Screenshot of some of the apps created by the students.

The most popular code template was for geolocate mapping. It was used by students to create apps for exploring public woodlands, industrial heritage and community learning resources (fig. 7.6, bottom centre). Another template was used to create a dictionary for translating yoga terms and postures from English to French and Sanskrit (fig. 7.6, left hand side). The same template was used to create a sports car gallery and an app recommending play activities for parents with young children (not pictured).

One advanced student created a working physics simulation, intended for use in teaching primary school students about collisions, forces, mass, velocity, restitution,

friction, and gravity (fig. 7.6, centre top). Finally, one student used another template to develop an app for retrieving and displaying college students' badges issued through the Open Badges API<sup>6</sup> (fig. 7.6, right). A badge is a graphical certificate of achievements, commonly used for gamification (Kapp, 2012, 89).

### 7.2.3 Views on future app development

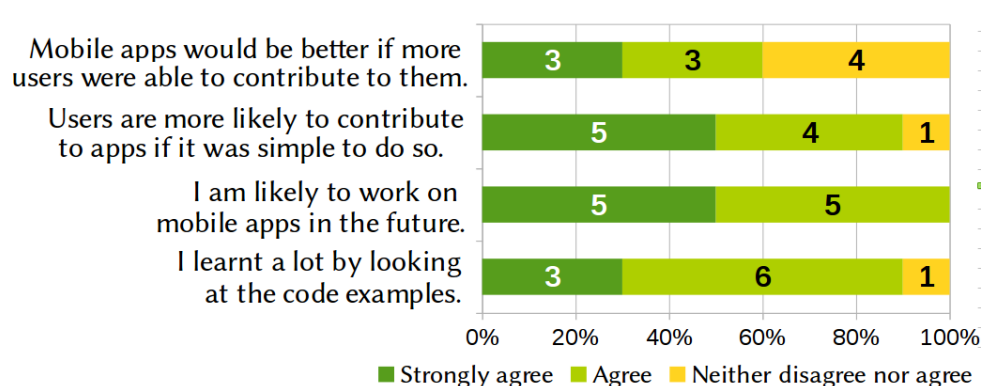


Figure 7.7: Participants' views on mobile app development.

Interestingly, all the respondents agreed that they were likely to work on apps in the future (fig. 7.7). For example, one of the students predicted that HTML5 app development will grow in popularity once more people learn about this approach:

“Apps are the new web design. I think once it gets around that you can design your own app more people will be interested. [–] I enjoyed working on my app and will keep improving it. And maybe think of a new project” (female, 35-44).

Another student indicated that he had enjoyed the course, highlighting the value

<sup>6</sup>[www.openbadges.org](http://www.openbadges.org)

of having the time to learn by trial and error, and that he wanted to continue to explore jQuery Mobile in the future:

“Plenty of time to investigate the software and experiment with code during the sessions, coupled with good one to one discussions with the tutor made for a very interactive learning experience. The course programme also gave a good insight into the development life cycle. I will certainly be investigating jQuery Mobile further.” (male, 25-34)

A majority of students agreed that they learnt a lot from looking at the code examples. This is an important result because the source code of HTML5 web apps can be easily readable (unlike native apps). Inspecting source code is a well-established learning strategy employed by many web designers. In contrast, opinion was divided about whether mobile apps would improve as a result of greater user contributions. Some students were vocal in their support:

“I passionately agree that users ought to be involved (I am a user) and I also believe that small scale community and voluntary sector groups should engage with new technology and learn how it might help them.” (female, 55-64)

Others felt less sure about whether a single user’s requirements and contributions would generalise to broader app audiences:

“Allowing contributions from users could be both positive and negative. The inclusion of some functionality by some users may not be useful for others.” (female, 35-43)

## 7.3 Part 2 - Use in stroke app development

This second part of the chapter explores the use of the second version of the Web App Editor (WAE) in the development of an app in stroke medicine. The project was carried out by Helen Mamalaki, a Masters in Informatics student in collaboration her supervisor and a consultant neurologist at a local hospital. She has consented to be named in the thesis. I was invited by Helen's supervisor to advise the project from the outset and suggested that she might want to test the WAE since she was developing a web app.

### 7.3.1 Methods and context

The aim of this part is not to analyse the stroke app, but rather to understand Helen's experience of using the WAE, and to explore her views about its role in medical app development and collaboration. To achieve this, I interviewed Helen at the final stages of completing the stroke app development process. I used a semi-structured interview (see appendix B.2) and analysed the findings thematically. Helen summarised her project in the following way:

"The purpose of the project was to create a web interface that elicit details of stroke patients, such as medical history and symptoms regarding their last stroke attack. [...] The information would be used to aid diagnosis and what treatment direction the doctor is going to use."



### 7.3.2 Helen's background

To establish the context, it is important to briefly outline Helen's background. She has an undergraduate degree in Computer Science and the six month stroke app project formed the basis for her dissertation for her Masters in Cognitive Science degree. One of the main reasons that she undertook the project was because she felt it could contribute to improving patient care in a practical way:

"I wanted to combine computer science with a discipline that focuses on [...] human well-being. Cognitive science studies how computational models help understand human cognition. This project was going to be used in a medical environment to improve [the care of stroke patients]. I liked the idea because it was more practical as opposed to research-oriented. Developing something that could be used; or if it doesn't get used, it provides a prototype that could be improved and [...] eventually used by real users."

When initiating the project, she already had some experience of web design. In the first year of her undergraduate degree, she had used HTML5, CSS and a small amount of Javascript (mainly jQuery) to create a simple website:

"We had to make a very simple website. It wasn't for data input, so it had no input forms or checkboxes. It was just a content display website on some of the module material. [...] It was part of my first year, so it wasn't very technically demanding. It was just HTML and CSS. I didn't actually use Javascript, although I used jQuery [Javascript library] code that I copied and pasted to make a funky menu."

During her undergraduate degree she had also created a language learning app using Java and the Android SDK (Software Development Kit). She reflected on her past experience of developing using web and native Android technologies:

“The Android SDK comes with a GUI [graphical user interface] that you can use to insert buttons and text boxes. I don’t remember there being any layout issues. But to be fair, we were designing it for a tiny mobile screen, so not many things fitted on the screen. Android doesn’t give you as much flexibility, in terms of what you can do [...] There’s huge flexibility with HTML [...] the more flexibility you have, the more things can go wrong and the more things you have to specify.”

In contrast to creating the Android app, she found laying out the first year website using Cascading Style Sheets (CSS) frustrating:

“Using CSS to create the layout was really, really annoying. I think I eventually managed to get it to do what I wanted it to do. [...] I don’t know if it is a limitation of how I knew to use CSS, but I knew [...] that getting something to go exactly where you want it to go on the screen – even though it may be simple – might be annoying.”

As she learned more about web technologies and related tools, she felt the web development experience was becoming less frustrating however:

“It is becoming less so as I get to know HTML5 more, especially the Chrome Developer Tools. They’re really helpful. I never used them before. [...] I knew it would be [...] a lot of minuscule changes and a lot of time spent on layout. [–] Having done [web design] once before, it was better and easier this time around.”

The stroke app project was also the first time she had used Javascript and libraries such as jQuery and Knockout<sup>7</sup> for making web-based applications, an experience she enjoyed:

“I did a little Javascript in first year. That was the language used to teach programming [...] I think javascript used in web programming is slightly different. I mean jQuery has a slightly different syntax. This is the first time I’ve used it for web programming purposes. I liked it. I thought it was easy to use, and there’s a lot of purpose built functions, for animations, for displaying content.”

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<sup>7</sup> Library for two-way data-binding based on the Model-View-Viewmodel pattern

### 7.3.3 Experience of using the Web App Editor (WAE)

On the whole, Helen enjoyed using the WAE and commented extensively on its strengths.

“I remember that when you showed it to me, I was just trying to understand what advantages it would have over the tools I was thinking of using. [–] I found the editor very valuable to my project. There are some features which I don’t know where else I would have found them.”

Helen used the editor to complete several tasks necessary to create the stroke symptom reporter app. She also suggested several improvements which will be discussed at the end. Figure 7.8 shows a screenshot of the stroke app being worked on in the WAE. Two screenshots of Helen’s final app are displayed in figures 7.9 through to 7.10.

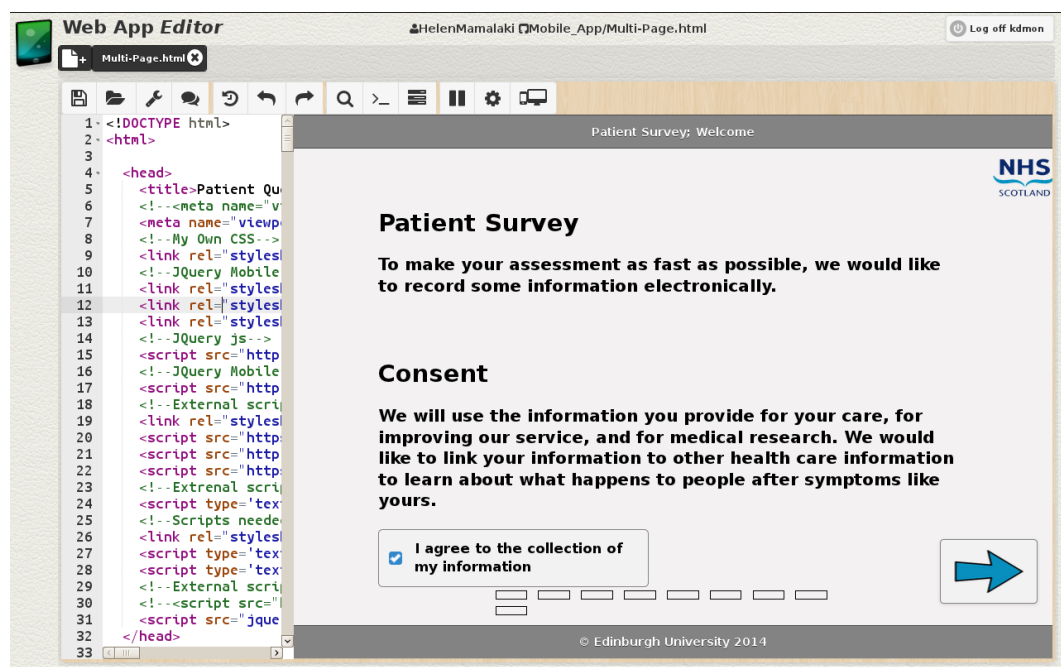


Figure 7.8: How the Web App Editor was used to develop the stroke app by activating the split-view mode, showing code and a live preview of the app. Screenshot used with permission of author.

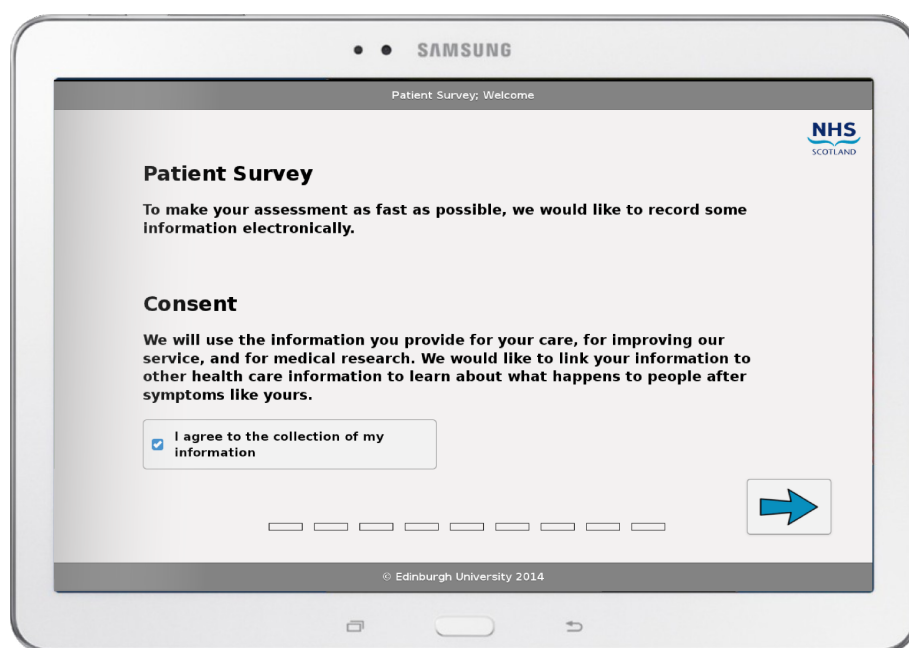


Figure 7.9: Opening screen of an app for recording the medical history of patients with stroke or transitory ischemic attack (TIA). Used with permission of author.

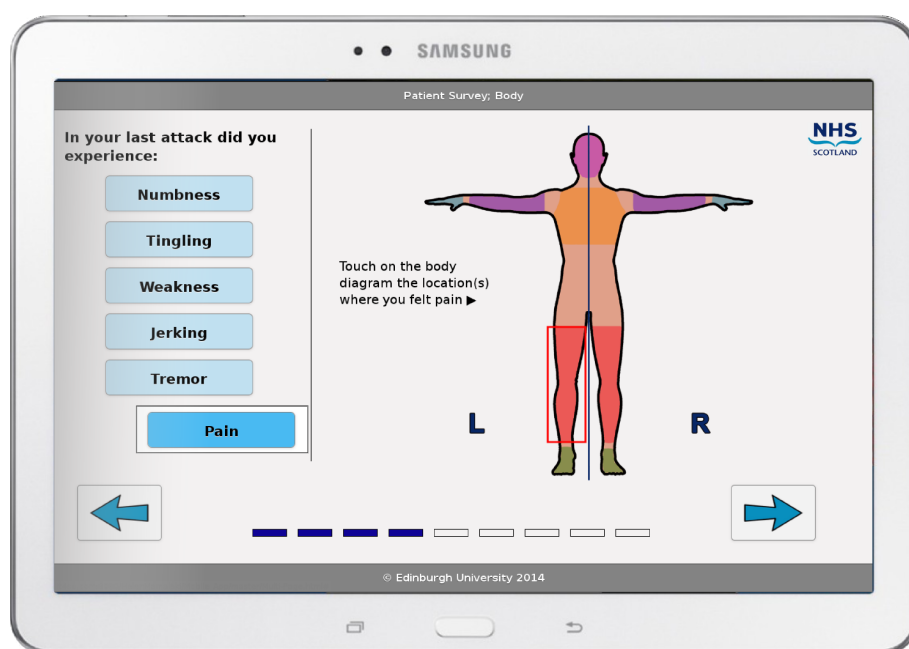


Figure 7.10: The app allows patients to visually indicate where on the body they experience symptoms. Screenshot used with permission of author.

### **Validating CSS and HTML syntax**

As was mentioned previously, the WAE is based on the ACE editor. It supports static code analysis and provides errors or warnings if programming language or scripting rules are violated. These are notified to the users in the margin of the code inside the editor. Helen felt that this feature significantly helped her to develop her app because it was easier to spot errors.

“I liked the highlighting [in the editor]. So a lot of the time I would copy and paste from Notepad into your editor to check the syntax because yours highlights the HTML syntax errors, because Notepad doesn’t. [...] Which was so helpful, as it would take me ages to find which closing tag I had missed out or deleted by accident. Usually I deleted a <div> tag by accident or missed an angle bracket, and it would screw up everything. As it is multipage app [a single, large file with thousands of lines] it was really hard to debug, and I don’t know what I would have done without the syntax checking in your editor.”

### **Auto-indenting and code folding**

Another feature of Ace is automatic parsing of code that enables the visibility code fragments to be selectively hidden from view (code folding). This makes it easier to concentrate attention to specific parts of the code, and to identify if the code is incorrectly parsed due to syntax errors. I implemented a feature (“beautify”) that would automatically indent code to make it more legible:

“I like the ‘beautify’ [feature] as well - that was really nice. Beautify basically indents the code so that each opening and closing tag is aligned, so it makes it much easier to [spot syntax errors]. Apart from the obvious, that it presents the code much more nicely (hence beautify) it makes it much easier to debug. It creates like a pyramid structure of opening and closing tags. So it’s more readable.”

### **Saving changes using version control**

Version control is a systematic way of managing changes to code using a dedicated software tool, such as Subversion, Mercurial or Git. Git is now widely used in software projects, not the least due to its popularisation by the website GitHub.com which offer additional collaboration features.

The version of the WAE that Helen used integrated with GitHub.com to allow code changes to be saved (called “commit” in Git) and retrieved easily, something that can be daunting to beginners as it involves typing commands, e.g:

```
git commit -am 'Test commit'; git push origin master.
```

Helen praised the simplicity of saving to Github with the WAE:

“One of the things that immediately became clear was that it was really easy to commit things. Especially as I had problems with committing using the GitHub Desktop application [...] I had figured out how to use Git in the terminal [by] entering lots of commands. So, it was so easy to commit – literally pushing a button!”

With version control, it is also easy to track changes to code over time (figure 7.11). GitHub also facilitates code discussions and an example is provided in figure 7.12 where Helen and I shared ideas to work out the best way to capture user’s reaction times on a touchscreen device.

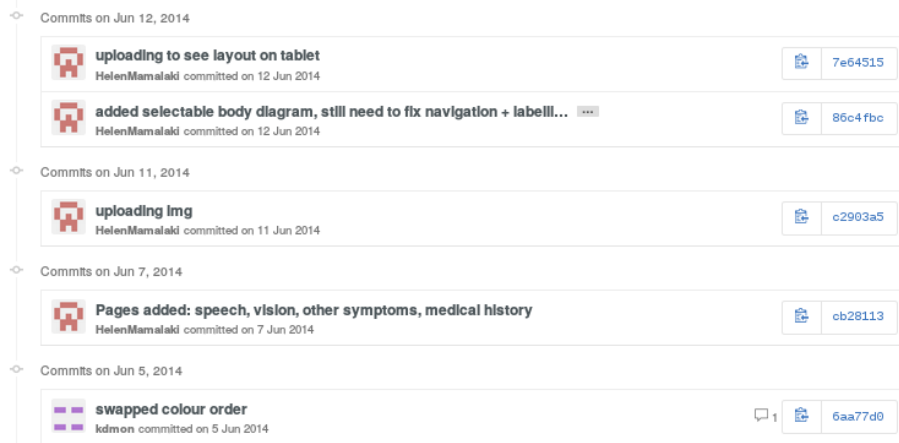


Figure 7.11: Example of Github's history of changes from Helen's project.

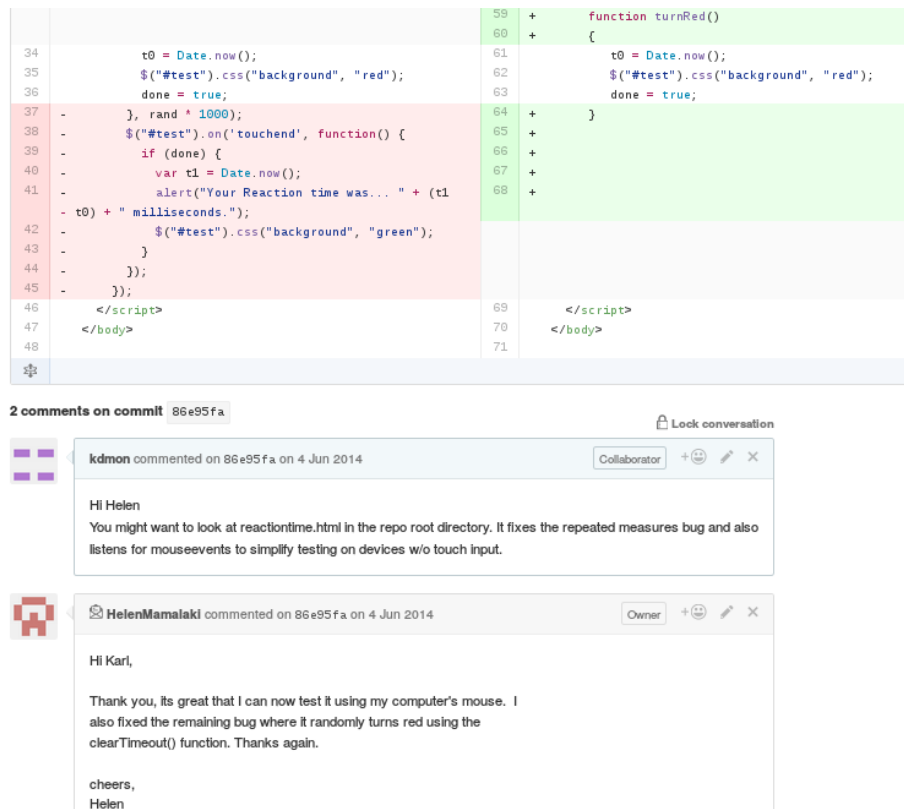


Figure 7.12: Discussing changes to the code in the stroke app on GitHub. Changes to the code are colour-coded (new, inserted code is green and old, removed code is red).

### **Instant preview on mobile devices**

Reducing the time from making a code change to seeing that change on the mobile device is critical for productive mobile app developers. The WAE has a server component that hosts applications as they are being worked on. A QR code with the web address of the application allowed Helen to quickly preview her work on a mobile device, or share a preview of the application with collaborators:

“I also like how it hosted my website. That was awesome (laughing). I like the quick [QR] code thing. That was really cool. [...] It was impressive how it almost transfers [the app] onto your phone, kind of like Chromecast, but not really. You can automatically load the web page on any device from your programming environment. So you can have your testing device separately from your computer where you’re programming using the editor.”

#### **7.3.4 Improvements**

The WAE is a work in progress and there are many areas of improvement. Helen’s feedback helped me realise just how important customisation is for users. Enabling settings such as editor font size, tab stops, syntax highlighting, colour theme and layout to be individually customised is critical to provide a good code editing experience. However, the settings dialogue was slightly difficult to find in the user interface:

“One thing that drew me back to notepad was something simple [...] I wish you could zoom in, increase the font size of the code. Whenever I open the code in Notepad, it would be so much more crisper and clearer because the font-size is much bigger. [Later, on discovering font-size setting] I really want to increase the font size right now. Oh, it looks more like Notepad now. [Changes colour themes] I like this one. I really like this feature. It does exactly what I want it to do”.



Similarly, Helen pointed out that other areas of the user interface could be improved and offered helpful suggests for how to re-organise it.

“... they’re very nice icons. But there’s a lot of learning involved. You have to figure out what they all are. I think there are quick tips, when you hover over the button it tells you what it does. That’s good. But a lot of the time it looks like a bunch of buttons and I have no ideas what they each do. I think it would be good to have the most commonly used features as buttons at the top. And then have submenus, like they do in the old Windows, where they had them under menus.”

### 7.3.5 Collaboration in medical apps

When I asked her about the role of collaboration in medical app projects, she explained that this is desirable and that using web technologies could enable patients to give feedback during software development and implementation processes:

“I think it would be a good thing to encourage collaboration. It would be great if users could give input. Because they could test the system before it is released [...] Since [the stroke app] is online, the NHS could just refer its patients to a demo or prototype website and ask: ‘What’s your feedback on this, we’re planning to introduce this in the NHS and would love your feedback’. That’s another advantages of having a health-related website available as open source. You have a huge population of testers available to you on the Internet.”

She also felt that developing medical software as open source was a good idea, but difficult to realise:

“I think it is a good idea [to make medical software available as open source]. But I think there are a lot of barriers not related to the actual code [...] I think a lot of the time the developer moves on. So that’s a problem, not related to the actual product. It needs to be someone who stays on to maintain, debug and oversee.”

When I asked her about whether she was going to make her code available under an open source license, she was positive about the prospect of others potentially re-using or improving her code:

“I haven’t really thought about it. I don’t expect anyone want to use my code as a template. But if they do, that’s fine. I’ll keep it public, so I guess I made that decision a while ago [...] It would be great if someone after me could come and improve the code, even if they point out things that I could have made better or debug certain things. That would be really useful and helpful for me to improve. So if I had to do this again from the beginning, I would know what to do differently.”

In fact, she later recalls that someone had asked her about reusing part of her code (shown in fig. 7.13):

“When I was presenting my project [...] I did get one supervisor saying that they were unable to access the code for the reaction time and pairs game for the UK Biobank, and they really wanted it [...] She was kind of “Would I be able to use your implementation?” because the UK Biobank didn’t make its implementation open to the public. So I thought that was really interesting, I’d be happy to do that. [—] It’s always flattering if someone wants to use your code work [—] as long as they refer to where they got the code from.”

However, Helen was hesitant about allowing commercial reuse or getting into a situation where people requested changes or code maintenance without appropriate remuneration:

“It’s different if someone wants to collaborate and contribute, versus someone who just want a finished product and who just want to use it. Because then that puts a lot of responsibility on me. I’d have to be there to maintain, debug it and alter it for their needs [...] Whereas if somebody wanted to do that for themselves, then obviously I wouldn’t have a problem with that. [—] It depends on how it was used [...] If it’s used in an NHS environment, I’m more happy. But if [they] are profiting from it, maybe if a private clinic wanted to use it, then I would want them to pay.”

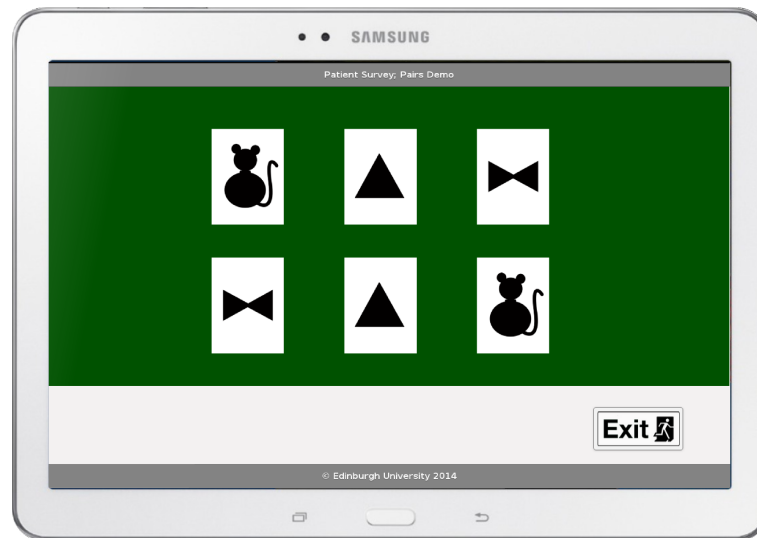


Figure 7.13: The stroke app measures cognitive function through built-in tasks. On this screen patients play a game of pairs, a test of short-term memory part of the UK BioBank test suite. Screenshot used with permission of author.

## 7.4 Discussion

Few app developers engage with users and current app development processes are often closed to users who are typically limited to review or rate apps (VisionMobile, 2013; Pagano and Walid, 2009). Similarly, when interviewing eleven medical device manufacturers Money et al. (2011) found that many were hesitant to collaborate with users during the design process. They identify several reasons for this, including:

- The conflation of the "customer" and the "user" (who, of course, typically have different needs, priorities and sway) and the decision to only engage with the former;
- The belief that less senior healthcare practitioners and patients are unable to pro-

vide valuable design input, and that engaging with them is a waste of resources;

- The shying away from research involving patients or changes to clinical care due to the inflexible and demanding nature of ethical regulations.
- A lack of appropriate collaborative design methods.

While it is important to acknowledge the reality that engaging with users can be difficult, and that they hold less sway than powerful gatekeepers or those directly funding a product, users can be an important source of domain knowledge and innovation. Who the users are, and their precise contributions, varies depending on the domain. For example, patients with rare diseases have developed new therapies for themselves (Oliveira et al., 2015) and healthcare practitioners have discovering new uses of existing drugs (DeMonaco et al., 2006).

In this study, I explore how one could encourage users of mobile apps to become more active contributors by making the collaborative app design process easier. Although efforts to simplify the app development process has come some way, the barriers to get started with native app development are still relatively high. This chapter has presented and evaluated a system designed to lower the barriers for beginners to create and contribute to web apps.

Ten students with little previous experience used the Web App Editor during two 12 week app development courses. During the two courses, the students created a diverse range of apps. Their feedback suggested that the editor was easy to use and that cre-

ating apps from code templates worked well. The online development environment enabled in-browser development and debugging of apps. It also did not require any special software, access to specific hardware or emulators. The development process was accelerated through the use of code examples and a supportive learning environment.

Following student requests, integration with the GitHub revision control system was added to the development environment. This allows code changes to be permanently committed, reviewed, branched, rolled back and merged in a controlled fashion. This approach is used by many open source projects and is useful for coordinating contributions from multiple authors.

#### **7.4.1 Future work and limitations**

The editor remains a work in progress and there are several features that could improve it further. For example, integrating with the Phonegap Build service would allow code to be retrieved directly from GitHub and make it easy to create native packages suitable for publishing on iOS, Android, Blackberry and other mobile operating systems. This would remove a manual step and make it easier to compile HTML5 app projects into native packages that can be distributed through the various app stores.

However, this features was not made available before the course finished, and was therefore not evaluated. Moreover, it was challenging to evaluate the quality of the

development environment in isolation from other aspects related to the delivery of the course, such as teaching approach and student backgrounds.

Furthermore, as the study was carried out at the end of the course, this may bias the results towards students who are more confident learners. I hope to be able to continue to develop the system further and test it with a larger user group under more rigorous conditions. Nonetheless, the development process described in this chapter could lend itself well to solicit app contributions from users. However, more research is required to investigate how this process can be made as simple and intuitive as possible for people who are new to app development.

## 7.5 Conclusion

There are many different stakeholders in medical app and medical device projects who have different needs, priorities and influence on the final outcome of the design process. Of course, those who use a mobile app or medical device are often different from those who commissioned, developed the specification, payed for it or built it.

Prior work have shown that users have limited means of becoming active contributors to the app and medical device design processes. While the value of the views, needs and priorities of the 'user' remains contentious among product developers, prior work in user-centered design and user-led innovation suggests that users may offer valuable input and can have a critical role to play in ensuring the outputs of the design

process meets the needs of the end users.

In this chapter, I presented and evaluate a new collaborative tool designed to simplify the collaborative app design process. The Web App Editor was well received by students in two introductory app development courses, and by a postgraduate student who used it to create an app intended to help patients communicate stroke symptoms. Hence, the WAE enabled novice app developers to learn about how web apps work and how they can be created and modified. It also enabled collaboration between students, who were encouraged to share their skills in the classroom.

Among the most important features was the live preview facility which enabled students to see and share work in progress with peers immediately. The use of version control enabled collaboration at the level of code and offered a tracked history of changes. However, feedback from the students suggested that the usability of the editor could be improved. This includes making the user interface more intuitive, such as highlighting the preferences.

In conclusion, with appropriate tools and support, those who are new to app development can pick up the skills to collaborate on mobile apps. This argument extends to healthcare practitioners who should be encouraged to acquire the skills to critically analyse and contribute to the mobile medical app that they increasingly rely on. More open app development environments and easy to use development tools can lower the barriers for users to participate in app development. However, it is important to recog-

nise the time, effort and commitment needed to develop programming skills required to make significant contributions and put strategies in place to support this.



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# **Chapter 8:**

## **Study 4: Usability Evaluation of the SBC App**

This chapter returns to the Special Blood Components app and discusses the usability study of the second revision (v.0.2) by 54 final year medical students. After outlining the background and evaluation methods, the students' ratings and feedback are discussed. The chapter concludes with a list of improvements and lessons learned, including reflections on the usefulness of remote evaluations.

## 8.1 Introduction

Following my presentation of the Special Blood Components (SBC) app at the British Blood Transfusion Society conference, I was invited by a course organiser at a UK university to evaluate the SBC app during a training day for final year medical students.

This was an excellent opportunity to collect feedback from an important user group. I reasoned that the students were likely to have experience of using mobile technology and would be aware of medical apps, but likely lack experience of prescribing or administering blood transfusions. Rather than to focus on students' knowledge of blood transfusion, the purpose of this opportunistic evaluation was to solicit feedback and measure the usability of the app.

Hence, previous experience of blood transfusion or special blood components was not a criteria when recruiting participants. Furthermore, I was interested in exploring the feasibility of evaluating the app remotely using an online feedback system incorporating web analytics. Thus, the purpose of this study was to evaluate the usability and content of the second revision of the Special Blood Components (SBC) app, and to identify further improvements to it.

## 8.2 Methods

This was an online evaluation study where the students accessed and evaluated the SBC app during two computer-based learning sessions on university premises.

The first session ran in the morning and the second in the afternoon. Students were split approximately equally between the morning and afternoon sessions. During both sessions, the training organisers circulated the URL of the app, instructing the students to explore it and then leave feedback using an online questionnaire.

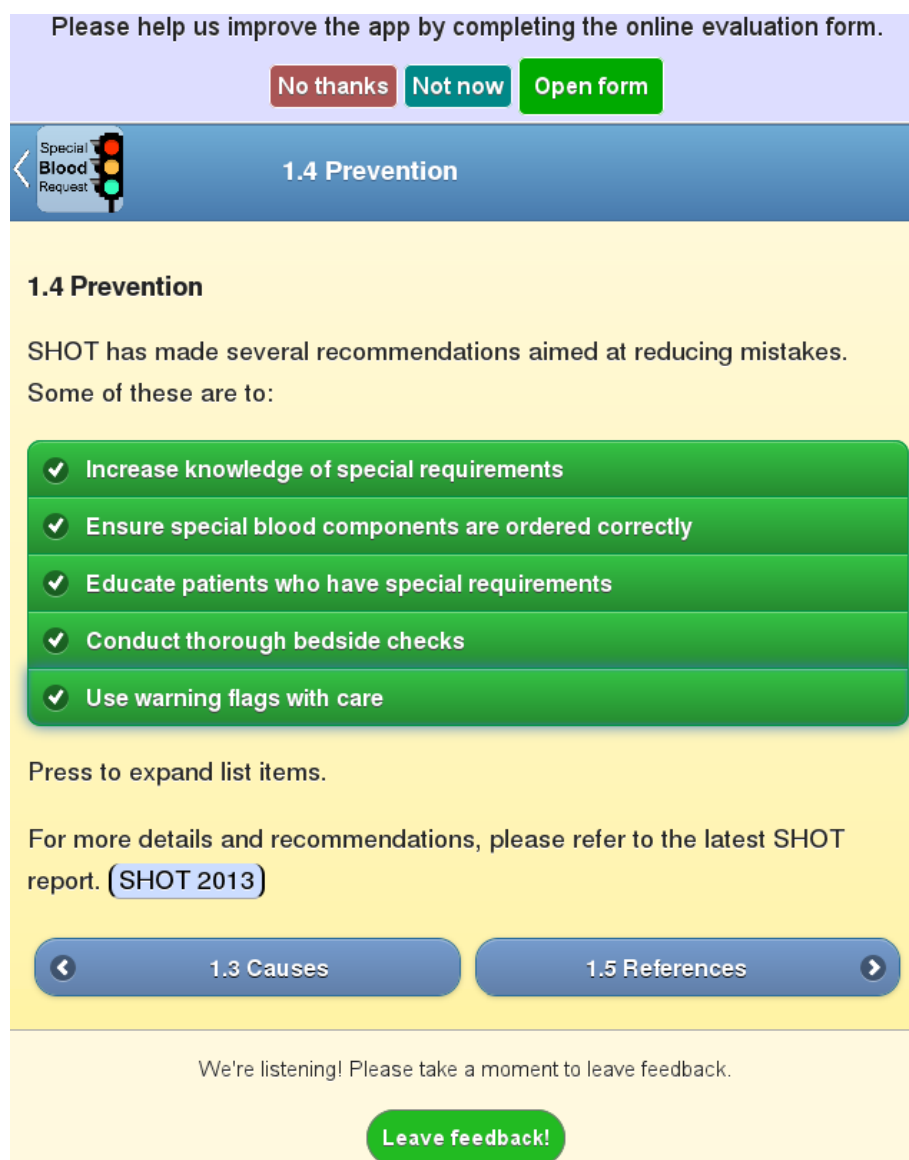


Figure 8.1: Sample page of the SBC v.0.2 app, showing in-app evaluation reminders (top and bottom) presented to respondents.

To improve the completion rate, a button linking to the questionnaire was displayed at the bottom of every page in the app. Additionally, after interacting with the app for five minutes, the app popped up a message reminding users to complete the questionnaire (see fig. 8.1). Users could dismiss this message completely, ask to be reminded later or click a button to open the questionnaire. None of the authors or contributors to the app were present during the training day. Nor were they acquainted with any of the participants, reducing risk of biasing the responses.

### 8.2.1 Online questionnaire

The evaluation questionnaire had four parts. The first part asked students to rate their overall impression of using the app and identify any problems. The second part of the questionnaire encouraged students to rate and comment on the sections of the app:

- The “information” section explained mistakes involving special blood components.
- The “indications” section listed the circumstances when special blood components are required according to national guidelines in the UK.
- The “checklist” section provided users with decision support through a question-based algorithm.
- The “quiz” section allowed users to test their knowledge of the indications by answering questions.

The third part of the questionnaire consisted of the System Usability Scale (SUS) (Brooke, 1996). This is a validated ten-item inventory that measures how easy a system is to use on a scale of 0-100. The final part of the questionnaire aimed to capture

students' experience of blood transfusion and demographic information such as age and smartphone experience. A copy of the questionnaire is provided in appendix C.3.

### 8.2.2 Remote monitoring

During the evaluation the use of the app was monitored. Data about which pages of the app were visited, for how long and using what computing device (operating system, screen resolution, browser) was collected and analysed using Google Analytics<sup>1</sup>. The data was analysed in conjunction with the questionnaire to better understand the strengths and weaknesses of the user experience.

The analytics service time-stamped important user interactions within the app, such as page navigation. By comparing the time between the first and last interaction, I estimated visit duration for all users. Google Analytics also provided an approximate geographical location (country and city level) based on the IP address of the user that was used to verify that only user sessions originating from the medical school were included in the analysis.

When a web browser requests the app for the first time Google Analytics assigns users a session identifier (a unique text string). This identifier is stored in as a browser cookie and was used to identify whether a visitor is a new user or a returning one, and to associate page events with that user. The cookie is insufficient to identify a person by name, unless it is correlated with other information, such as personal information

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<sup>1</sup><https://analytics.google.com>

voluntarily divulged by the respondent. Participants were provided with information that explained what data was recorded and why (see appendix C.2).

## 8.3 Results and discussion

Approximately 270 final year medical students attended the training day. Google Analytics recorded 186 unique visits to the app originating from the city where the training was taking place. This suggests close to 70% (186/270) of the attending final year students opened the app. Of these, 65 students provided evaluation feedback. Only 54 responses were sufficiently completed for analysis, yielding an effective response rate of about 29%, based on unique visits (54/186). For the system usability scale (SUS) inventory, only 40 responses could be included in the analysis due to incomplete answers.

### 8.3.1 Respondent demographics

All respondents were aged 20-29, except for one person who was in the 30-39 age group. With the exception of one foundation year 1 (FY1) trainee, the respondents were all final year medical students. The FY1 was included in the analysis.

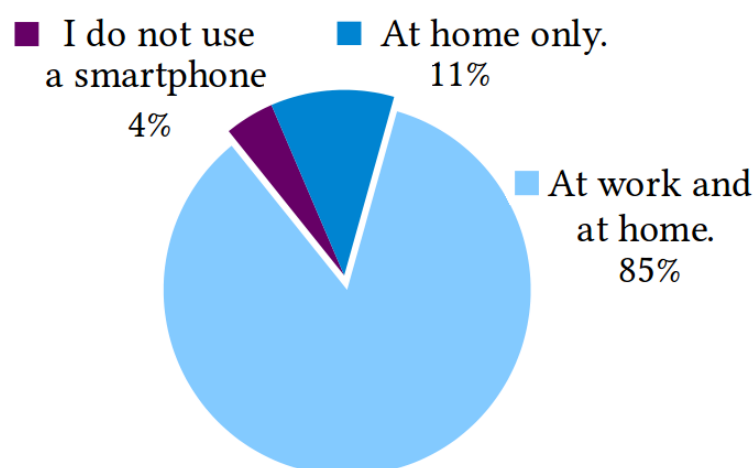


Figure 8.2: Smartphone use among final year medical students. Base: 42 respondents who answered the question “Do you use a smartphone?”

When asked if they use a smartphone, 85% (39/42) indicated that they use a smartphone both at home and at work (fig 8.2). This is in line with other surveys of smartphone adoption among medical students (Payne et al., 2012). However, only six participants accessed the app on their smartphones according to Google Analytics. The others accessed the app on desktop computers running Microsoft Windows with the Google Chrome (version 31) or Microsoft Internet Explorer (v.10) web browsers.

### 8.3.2 Blood transfusion experience

The large majority did not regularly carry out responsibilities related to blood transfusions. Only 12% (5/42) indicated that they were involved in blood transfusions on a monthly or more frequent basis. Fewer still, 7% (3/42), reported working with patients requiring irradiated or CMV-negative blood components.



When asked about irradiated and CMV-negative blood components, 40% (17/43) felt they were not confident about the indications for special blood components. Only a quarter of respondents (11/43) felt that the guidance for special components was easy to use, and 70% (30/43) agreed that having an app for special components would be useful.

### 8.3.3 App interaction times

Across all 186 unique visits, the app was accessed for an average of duration of eight minutes. Among the 54 respondents to the questionnaire, the average duration was just over 10 minutes and the median duration was close to eight minutes (range: 1m 20s to 38m; s.d: 9m). Figure 8.3 summarises their interaction times for the 54 respondents.

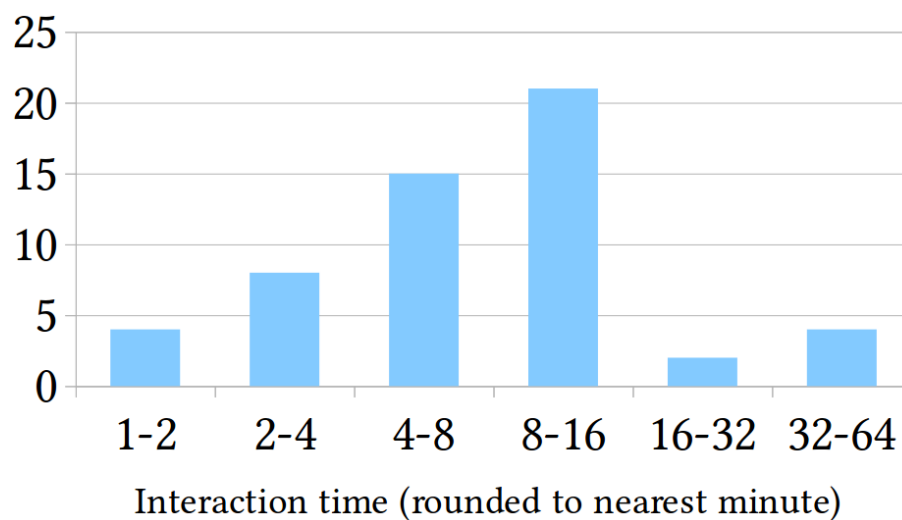


Figure 8.3: Frequency distribution of the 54 medical students' interaction times using exponential bins (rounded to nearest minute). Multiple sessions belonging to the same user have been collapsed.

### 8.3.4 App ratings

The app generated a mixed response. The comments ranged from positive (“The app was quite useful.”) to negative (“Overall [I am] very disappointed in this app and [I] do not see it being used.”). When asked to indicate their overall reaction to the app (fig. 8.4), over 80% (44/54) agreed or strongly agreed that they could see a use for the app and 62% (32/54) would recommend it to others. Furthermore, just over half of the respondents (27/52) felt that their experience of using the app had been enjoyable and nearly a quarter (12/52) reported the reverse. Close to half the students (25/54) believed that they were likely to use the app in the future, but 35% (19/54) thought it unlikely.

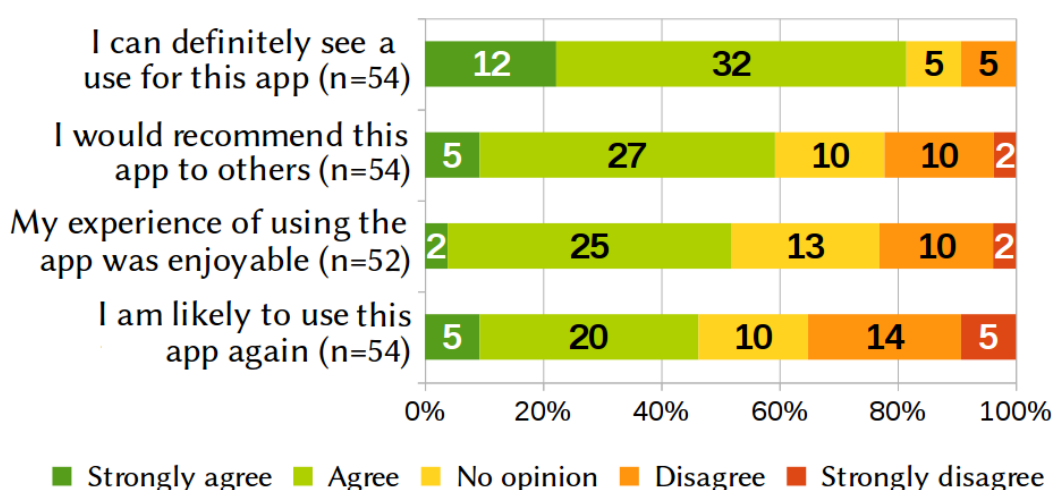


Figure 8.4: Overall ratings for the SBC app (v.0.2).

This polarised response is likely due in part to factors extrinsic to the design of the app. Several respondents cited unfamiliarity with the topic and difficulty of taking in all the information in the app. For example:

“This was so detailed compared to any teaching we have had before as medical students, so to try and remember the exact type of irradiation/CMV for each indication seemed far too complex. Well-designed and clear though.”

As respondents were final year medical students with little knowledge or experience of special blood components, some respondents felt that the app was beyond the scope of their current role:

“The app is useful, however, the information provided seems more useful for specialist registrar level as opposed to medical student level.”

“I feel that this app probably aims above the level of a medical student.”

Some local hospital guidelines reduce the information to a simple list of indications that fit on one page. However, the app aims to reflect the national guidelines, which are relatively complex and lengthy. There is a trade off between a simple app that demands minimal attention and one that aims to reflect the national guidelines more fully. It is encouraging that the app was rated very favourably by three respondents who reported caring for patients with special requirements on a daily or weekly basis.

### **8.3.5 The information section**

Judging by the Google Analytics data, most respondents appeared to go through the app systematically, starting with section one which covers background information. The ratings (fig. 8.5) show that the information section was well-received. 90% (45/50) of respondents felt it was worth reading and 75% (38/51) agreed that it was succinct and easy to read.

### How would you describe the "information" section of the app?

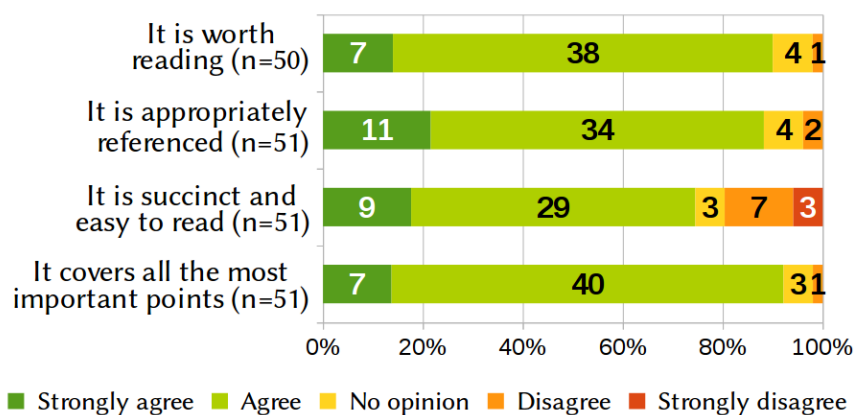


Figure 8.5: Ratings for the “information” section of the app. Answers to the question “How would you describe the ‘information’ section?”.

That said, several respondents provided comments related to the amount of content. Some, who had clearly given the contents of the app some careful thought, asked for more details, such as:

“Why do you have to irradiate blood from first or second degree relatives?”

“[The app] needs to explain the risks rather than just say how to avoid them.”

“There wasn’t a good introduction explaining the need for CMV-negative and irradiated blood products. If I understood the mechanism behind this I would be more likely to be able to give an educated guess for what is required, rather than [relying on] ‘pattern recognition’.”

The latter comments highlights the rationale for introducing the information section: to go beyond a simple list of indications to something that could provide users with a deeper understanding of the subject. However, to provide adequate answers to the questions raised above would require an extended information section. At the same time, many respondents requested even more summarised information:

“The app had a lot of information which wasn’t very easily accessible.” “There are a lot of big chunks to read which are off putting.” “There was too much information to pull out the main points quickly, which is what an app like this should be for.” “I found there was quite a lot on information of the one page, which made it difficult to get through and focus on each section.”

In domains with high levels of complexity, such as healthcare processes, bad design can make users feel things are more complicated than they need to be. But even the best design cannot remove the underlying complexity (c.f [Norman, 2011](#)). Hence, it is important to remember that the app cannot be a replacement for users taking the necessary time to learn about the subject in sufficient depth. Some suggestions for how the content might be structured differently to make it easier to take in were offered by participants:

“Maybe have summaries of which conditions require certain types of transfusions.”

“The information could also have been grouped into CMV-negative and irradiated blood and listed which conditions require which rather than the other way around.”

Other options might be to have a frequently asked questions and links to further online learning resources. For example, the Blood Bank Guy website has a good video explanation of the role of shared HLA haplotypes between close family members in developing Graft versus Host Disease ([Chaffin](#), no year).

Additionally, indicating the time requirement that the app places upon the user could perhaps manage their expectations. For example, if it is made clear upfront that

it will take 10 minutes to get through the background information section, it may be more acceptable to users and make it easier for them to manage their time.

### 8.3.6 The indications section

70% of respondents felt that it was easy and quick to look up the indications for irradiated and CMV-negative components (Fig. 8.6). Even participants who were otherwise quite negative about the app felt that the indications section was valuable:

“[The indications section is the] only useful section and one that I would use again on the ward if I was unsure.”

“The indications section should be published on it’s own to be accessed by hospital staff and medical students as it was very useful. Bin the rest.”

Only 6% (3/50) of respondents felt that the indications were unclear. This is positive because presenting indications in an unambiguous way that is true to the original national guidelines was an important design goal.

#### How would you describe the "indications" section of the app?

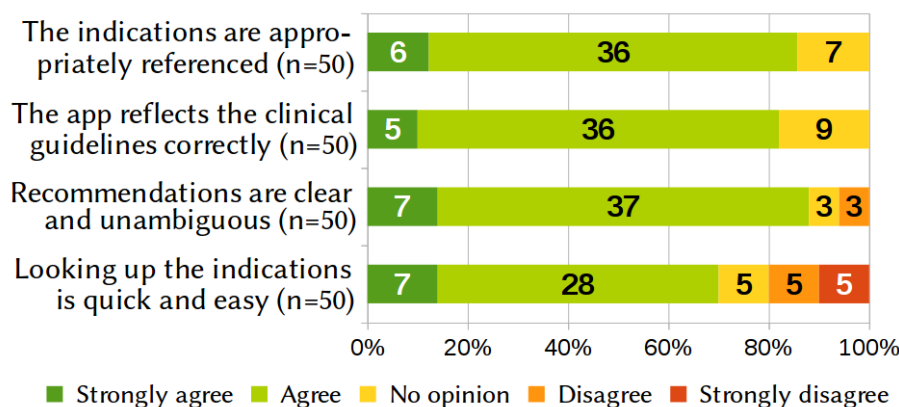


Figure 8.6: Ratings for the “indications” section of the app. Answers to the question “How would you describe the ‘indications’ section?”.

Moreover, it is necessary that medical apps cite their sources so that users can verify the claims made in the apps by consulting the original source. Adhering to this principle can ensure that apps build on current medical knowledge.

None of the respondents felt that the app failed to reflect national guidelines or was poorly referenced. However, one participant felt that the way the app cited its sources could be toned down to make the main text easier to focus on:

“I don’t know if references are the most important thing about an app like this. The text makes everything seem too busy.”

Another criticism was the way that the indications were laid out, and the resulting back and forward navigation required to explore details of multiple indications:

“The information is relevant and useful and very clear. However, I think the format of going back and forth is time-consuming.”

### **8.3.7 The checklist section**

The checklist section is essentially an algorithm which aims to identify what, if any, indications for special blood components are likely to be relevant in a particular scenario. This is achieved by asking two simple questions and providing a restricted set of answers: what blood component is to be transfused and who will receive it?

Although two thirds (33/50) agreed it was logically structured, and almost as many (32/50) felt it was quick and easy to use (Fig. 8.7), several students felt they struggled to understand the purpose of the checklist:

“I did not understand what I was meant to do here and what the function of this section was.”

“Section three is dubious and unclear. I thought that was what a checklist is: something you can check if you are unsure.”

“I wasn’t sure how the checklist section was meant to work. It said to answer a question, but I wasn’t sure what the question was supposed to be. It also kept sending me back to the indications page, which was annoying when I just wanted to get back to the checklist.”

#### How would you describe the "checklist" section of the app?

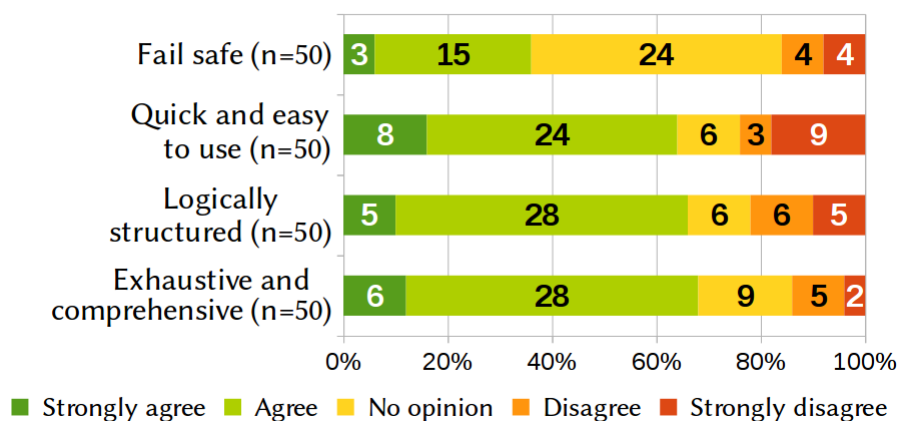


Figure 8.7: Ratings for the “checklist” section of the app. Answers to the question “How would you describe the ‘checklist’ section?”.

As with the information section above, it appeared that some respondents felt overloaded with information and that this got in the way of using the checklist effectively:

“Again I found there was a lot on information on the one page, a lot of the headings were similarly named and I found it a bit confusing to work through. The information contained was good, but it was exhaustive and I felt I got a bit lost while I worked my way down the checklist.”

“It is logically laid out, but the list is a bit too clunky. Some of the information takes a bit of time to find.”

The challenges of designing a checklist are quite similar to those related to the



information section. It has to be quick and easy to use, yet be comprehensive to generate a result which is reliable, or at the very least unlikely to cause harm. In relation to this point, one of the students made a perceptive comment of the pitfalls of relying on “fail-safe” cognitive aids in complex cases:

“[There is] no such thing as fail safe, complex issues will always throw a spanner in the works.”

### 8.3.8 The quiz section

Most respondents were positively inclined towards the quiz, with 77% (36/47) agreeing that it was an useful way of learning and nearly as many (35/47) felt that the questions were well-phrased (fig. 8.8).

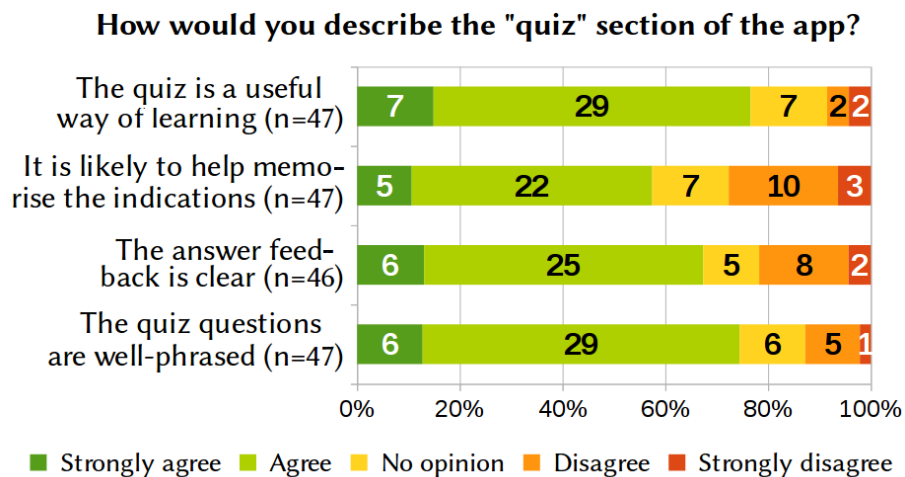


Figure 8.8: Ratings for the “quiz” section of the app. Answers to the question “How would you describe the ‘quiz’ section?”.

However, many students provided feedback suggesting how the section could be improved and expanded. Most notably by providing a total score to allow users to check their performance:

“Quiz loops after completion. Consider showing results of questions, allow for identification of areas of ignorance.”

“It would be helpful if you could get a score on the quiz part of the app.”

“I would have liked a summary of my answers and overall score for the quiz at the end.”

Others requested more detailed feedback, explaining why each answer is correct or incorrect:

“Quiz could be more useful with reasons why answers are right or wrong. Also a summary page to show all questions answered would be useful.”

“It could elaborate slightly more on reasons for certain answers.”

“More information in the answers section as to why each answer was correct or incorrect would be helpful.”

Several students also commented that the phrasing of some of the questions could be improved:

“Some questions were repeats of the same theme with different parameters, which didn’t help interest.”

“Two questions in the quiz were duplicated.”

“I didn’t think the phrase ‘how should they be transfused’ was very clear.”

### **8.3.9 Interaction design**

Comments provided by participants about the app’s user interface design and layout were mixed:

“Useful app structure, fast and easy to use UI [user interface]”

“The app had a very complicated layout and was difficult to navigate effectively.”

Many respondents felt that the navigation was cumbersome, with six respondents feeling that there was too much back and forward navigation. It is important to remember that students mainly accessed the app, which is optimised for smartphone use, through desktop computers. These typically have large screens, which are better suited to larger sections of text that a user can skim, compared to the smaller a smartphone or tablet screens, where multiple pages might be more suitable.

Hence, device form factor may account partly for these comments. That said, it is possible to optimise common navigational paths and eliminate some steps. A couple of comments suggested alternative layouts that might improve usability:

“I would recommend perhaps dragging options into one of the 5 categories (since there are always the same options), or simply going through each one, so clicking next from the first one takes you onto the second one.”

“Might be better to use expanding menus rather than a new page since it can be confusing to go back and forth. Or perhaps making a table to further clear things up?”

There were also a couple of interaction niggles identified by the students, including:

“...when you go back, it automatically goes back to the top of the page, so you have to scroll down to where you were again which is a bit annoying.”

“[In the indications section there was] no back or back to top button at bottom [causing] needless scrolling.”

### 8.3.10 Usability score

The system usability scale (SUS), based on 40 completed submissions, yielded a score of 63 on a scale of zero to a hundred. This is not a simple percentage score, but should be interpreted as a score that has to be “graded on a curve”, as commonly done in university marking. Thus, average SUS scores are somewhere around 68-70, the failure threshold is around 50 and excellent scores are in the 80s and 90s (Sauro, 2011; Bangor et al., 2008, p. 592).

The app scored below average, but well above the failure or unacceptable threshold. In short, the SUS rating, together with the other ratings and feedback, suggests that there is room for usability improvement.

## 8.4 Conclusion

This study has provided valuable usability evaluation data from potential users. The students identified a number of shortcomings in the design of the SBC app that required additional work to address. A summary of the areas of improvements is provided in table 8.1.

Despite these weaknesses, many of which were addressed in the subsequent version, the app received an acceptable score on the system usability scale. Additionally, the use of a remote evaluation survey exceeded expectations as the collected data was quite rich and insightful.

The flexibility of evaluating medical apps online opens up opportunities to more easily integrate formative evaluation into the app development process. However, an important limitation in this study was that most of the students lacked experience of blood transfusions

Furthermore, it was an open-ended evaluation which took place without a strong task context. It is possible that respondents with more experience, and who would have been given explicit patient scenarios to consider, would have evaluated the app more critically. Thus, in the next and final study, more experienced healthcare practitioners were invited to evaluate the SBC app using patient scenarios.

Table 8.1: Summary of areas of improvement identified by the students.

Content	Make the content more concise and include additional learning materials, including more information on the rationale for special blood components.
Quiz	The quiz was a valued feature that many students requested to be expanded with more detailed scoring and feedback.
Task efficiency	Students felt that there were too many navigational events required to access the information. It is possible to reduce some of these. For example, the indications table could be converted into an accordion menu that expands and contracts information without triggering a page refresh.
Usability	The strong highlighting of references got in the way of reading the information. Referencing colour style should be made more subtle. Excessive scrolling and vertical jumping on some pages requires fixing. The checklist section was difficult to understand and use for many respondents.

# **Chapter 9:**

## **Study 5: A Randomised Controlled Pilot of the SBC App**

This chapter presents a web-based randomised controlled pilot study of the revised Special Blood Components (SBC) app with healthcare practitioners. The chapter is structured in line with the main principles of the CONSORT guidelines for reporting randomised controlled clinical trials (Schulz et al., 2010) as adapted to eHealth interventions (Eysenbach et al., 2011). It begins by describing the features of the revised Special Blood Components (SBC) App, methodological considerations, research questions and methods. This is followed by the presentation of the main results, the discussion and the conclusion.

## 9.1 Introduction

As mentioned in previous chapters, the impacts of healthcare technology cannot be taken as “given” and require systematic empirical research. Yet, few eHealth interventions and medical apps for healthcare practitioners have been rigorously evaluated.

This study examines the second major revision of the SBC app (v.0.2 November 2014) which featured a re-designed graphical user interface, expanded learning materials, global search and faster access to the clinical indications for special blood components (see screenshot in figure 9.1).

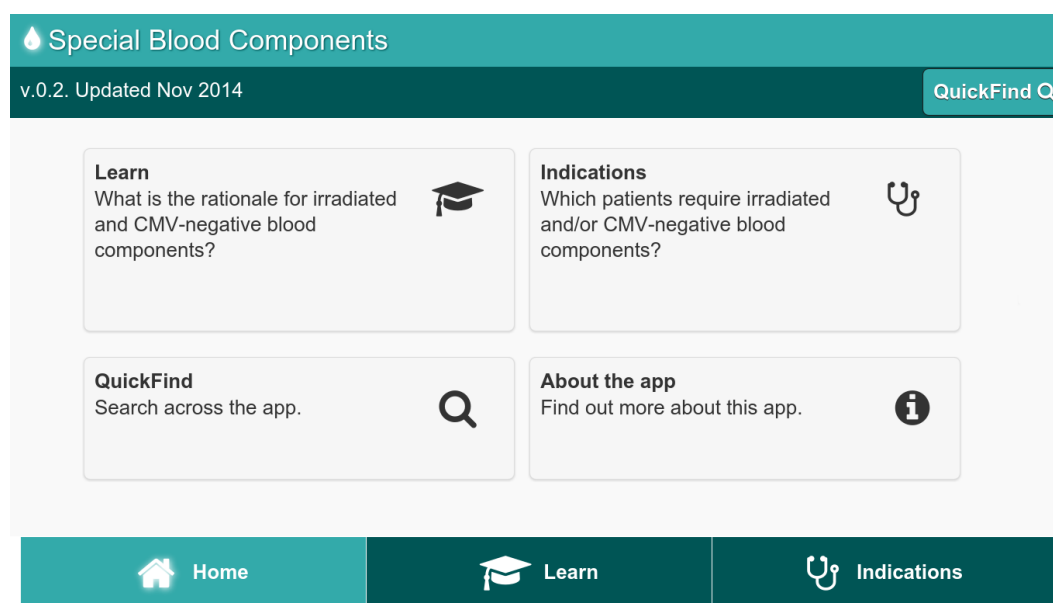


Figure 9.1: Main screen of the second revision of the SBC app, rendered on a wide screen display in landscape orientation.

Furthermore, the revised app followed better coding and design principles, including responsive design and graceful degradation. That is to say, different screen reso-

lutions were better supported through the use of CSS media queries, ensuring an improved user experience on desktop, tablet and smartphone devices. Greater emphasis on the educational aspect of the app, which was highlighted in the usability evaluation with the final year medical students (reported in the previous chapter), resulted in an expanded learning section.

Additionally, the “checklist” page, enabling relevant clinical indications to be identified by answering two questions, was excluded because participants in the previous study found it unintuitive. Similarly, the built-in “quiz” was temporarily removed because its questions were almost identical to those that would be put to participants as part of the study’s knowledge test, and could thus cause confusion or an unfair advantage. The aim of the SBC app remained the same as before: to promote the correct use of irradiated and Cytomegalovirus (CMV) negative blood components by providing practitioners with quick and easy access to the clinical indications and learning materials. With this aim in mind, possible research designs were considered.

### **9.1.1 Methodological considerations**

A common criticisms leveled at evaluations of eHealth initiatives is their failure to assess clinically meaningful outcomes. Hence, the “gold standard” for demonstrating the effectiveness of the SBC app was carefully considered. One such measure, for example, is the number of patients with special requirements who incorrectly received



non-irradiated or CMV-random blood before and after introducing the app to practitioners in a ward.

Unfortunately, training practitioners and auditing patients with special transfusion requirements was beyond the scope and resource constraints of the project. Given the stringent ethical regulations that govern who can retrieve and analyse patient data, this research design would require recruiting a member of NHS staff to analyse the data, which was not possible.

Furthermore, it would still be challenging to attribute changes in clinician behaviour and rates of mistakes to the design of the app, and rule out the effect of existing training and other sources of uncontrolled variation. For example, mistakes involving blood transfusion often have multiple causes and involve human factors explanations, such as distractions in the workplace.

For these reasons, I decided to abandon direct clinical outcomes and attempt to instead evaluate the impact of the SBC app on practitioner knowledge. As an educational aid that complements existing transfusion training, the SBC app should be an easy to use intervention that enhances understanding of the importance and rationale for using irradiated and CMV-negative blood components with healthcare practitioners.

Although e-learning is an established part of many medical education programs, the effectiveness of Internet-based learning interventions in continuing medical education has rarely been explored. For instance, [Curran and Fleet \(2005\)](#) reviewed 86

studies published before December 2003 that pertained to Internet-mediated continuing medical education for doctors. Only 31 studies provided some level of evaluation and the other 55 studies were descriptive in nature. Of the 31 studies, most assessed learner satisfaction and about half assessed learning outcomes (knowledge). Only two studies assessed whether the intervention lead to changes in clinical practice. None of the studies assessed the effectiveness of the training interventions on actual patient and healthcare outcomes measures.

There are many methods for assessing medical knowledge, each with their strengths and weaknesses (Cox and Irby, 2007). The concept of “competence” is frequently used as a measure of a person’s suitability to carry out medical procedures, and includes not just basic knowledge, but also other dimensions such as observed practical skills, patient care, professionalism, reflection and self-awareness (Cox and Irby, 2007). These latter aspects are more difficult to gauge.

Adapting Donald Kirkpatrick’s influential “four levels” model for training evaluation (Kirkpatrick and Kirkpatrick, 1994), Curran and Fleet (2005, 563) suggest that web-based medical education interventions can be assessed using the following levels: learner satisfaction, learner outcomes (knowledge), performance improvement (behaviour) and patient/health outcomes (results). Bates (2004) offers a critique of Kirkpatrick’s four levels model, arguing that it lacks supporting evidence for the causal relationships between the four levels of the model. Furthermore, they argue that the

model ignores other possible evaluation criteria and contextual factors that influence the impact of training programs. Despite these criticism, the model provides a useful way of thinking about some of the possible dimensions of an educational intervention.

## 9.2 Methods

Having previously refined the SBC app according to mostly qualitative feedback, the purpose of this study was to quantitatively assess the two first levels of Kirkpatrick's evaluation model: acceptability and impact on practitioner knowledge.

The study assessed these aspects using a pre-post parallel groups research design involving doctors, nurses and biomedical scientists who had completed the Safe Transfusion Practice module of the Learn Blood Transfusion in the previous twelve months. The evaluation followed a pragmatic web-based parallel groups randomised controlled study design, summarised in figure 9.2.

Participants were allocated to the SBC app or guidelines using stratified randomisation to balance the effect of professional experience. Knowledge was measured through two eight item multiple-choice tests, completed before and after the SBC app or guidelines was made available to participants. After completing the baseline test, participants could make use of the allocated intervention, which was displayed adjacent to the remaining questions. Ratings of the app and guidelines were captured using five point likert scales measuring the ease of finding information, enjoyment, likelihood

to use again and to recommend to others. A copy of the questions are provided in appendix D.5.

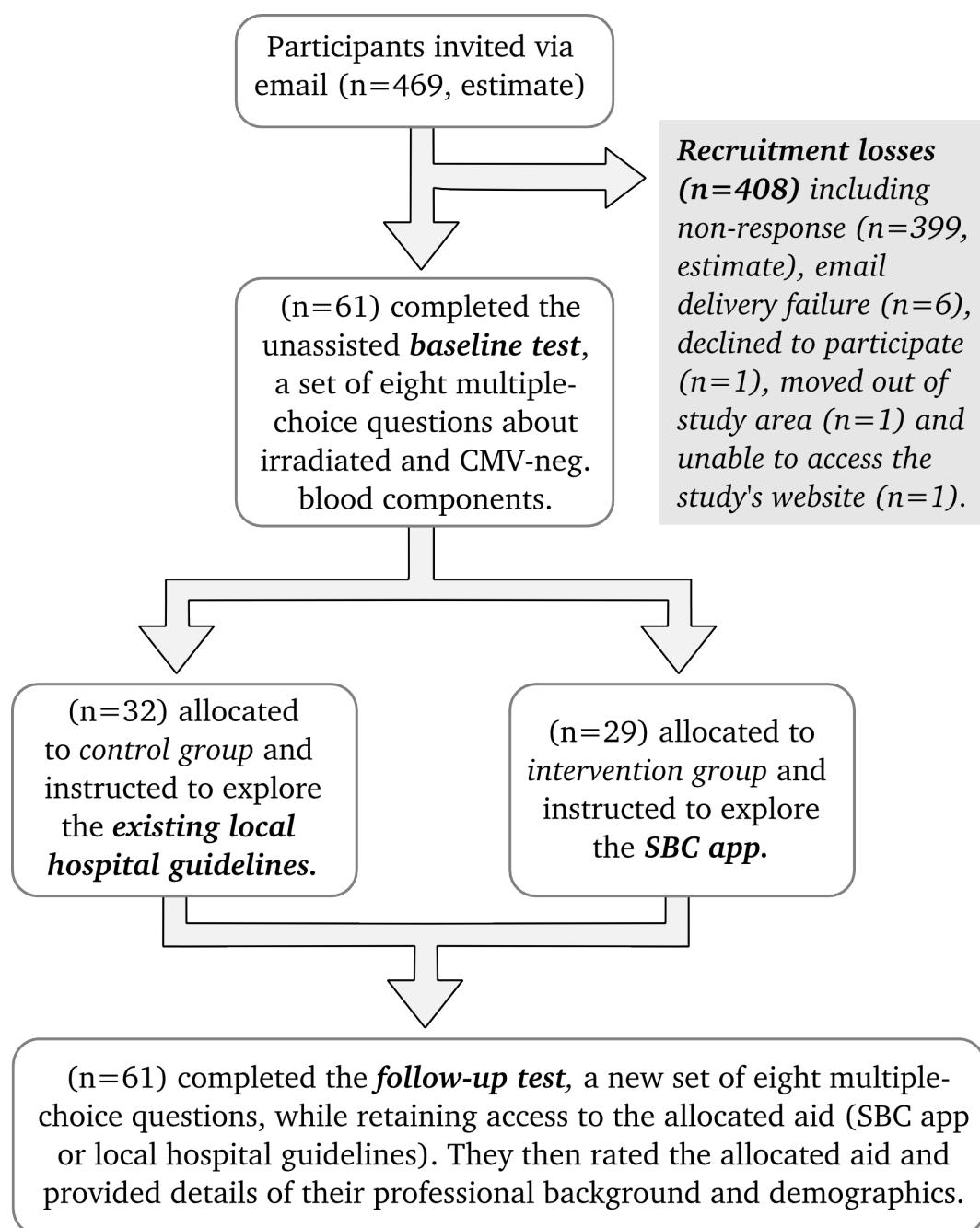


Figure 9.2: Study design.

### 9.2.1 Selection of control treatment

Local hospital guidelines that contain a list of the clinical indications were selected as control treatment because they represent the current practice in the hospitals. The guidelines were converted from a Microsoft Word document to a web page that was easy to search, supported by current web browsers and could be embedded in the study's web-based interface.

### 9.2.2 Outcome measures and hypothesis

This study assessed acceptability and efficacy on practitioner knowledge. The following hypotheses were tested:

**H1: There is a significant difference in the efficacy of the SBC app and existing hospital guidelines on participants' knowledge of the correct use of irradiated and CMV-negative blood components. (primary outcome)**

**H2: There is a significant difference in the acceptability of the SBC app and existing hospital guidelines. (secondary outcome)**

Efficacy was defined as the change (learning gain) in practitioners' knowledge of irradiated and CMV-negative blood components as measured through multiple-choice tests administered before and after using the app or guidelines (pre-post-gain). The tests were composed from two sets of eight questions designed to probe knowledge underpinning correct clinical practice (see appendix D.5). To minimise spurious learning gain, the test questions were ordered randomly. For the same reason, no answer feedback was provided to participants.

Acceptability was assessed through written feedback and likert scale ratings examining four dimensions: ease of finding information, enjoyment of use, desire to use again and likelihood to recommend to others. Acceptability ratings were analysed with the Mann-Whitney U test and aggregated to create a single acceptability index with a scale of 0-100. Within-group learning gain was analysed with the T-Test and between-group differences were analysed using generalised linear models (GLM) controlling for baseline knowledge scores. All statistical analyses were conducted in the R software v. 3.0.2 (R Team, 2013).

It should be noted that knowledge retention is a key indicator for assessing the effectiveness of educational interventions, and this aspect was originally one of the outcome measures included in the study. However, investigating knowledge retention proved infeasible since less than half of those who took part in the study (29/61) expressed interest in participating in a follow-up study. Even with a low attrition rate, a follow-up study would likely be unsuccessful in recruiting sufficient numbers of participants to draw meaningful conclusions.

### 9.2.3 Population and sampling

All healthcare practitioners involved in blood transfusion in Scotland are required to complete Module 1 (“Safe Transfusion Practice”) of the Learn Blood Transfusion (LBT) online e-learning programme at least biannually.

Table 9.1: Sampling frame, grouped by professional role.

	Nurses, midwives and theater practitioners	Doctors (all grades)	Biomedical scientists	Total
Trained transfusion staff *	2727	981	45	3753
Invited **	219 (8.0%)	244 (24.9%)	6 (13.3%)	469 (12.5%)
Responded	19 (8.7%)	37 (15.2%)	5 (83.3%)	61 (13%)

\* Estimate based on staff within the sampled health board who completed one of the following Learn Blood Transfusion modules between 1 March 2012 and 31 August 2014:

- Module 1 Safe transfusion practice (aimed at all staff groups).
- Module 1 Safe transfusion practice for Paediatrics.
- Transfusion Laboratory - Safe Practice Module.

\*\* Approximation calculated from the 336 direct personal email invitations and 133 (estimated) invitations sent via local hospital deaneries.

Working with the Better Blood Transfusion Team at the Scottish National Blood Transfusion Service (SNBTS), I was able to identify participants through this programme. Measures, including encryption of data, were put in place to protect the personal data of participants and minimise any unsolicited email communication. Copies of the email messages sent to participants, and the participant information sheet, are provided in appendix D. An estimate of the sampling frame is offered in table 9.1.

### 9.2.4 Power calculation

A total target sample size of 68 was derived based on the primary outcome measure (difference in learning gain between the arms). This value was calculated using the GPower (v.3.1.9) software with the following parameters: a priori power analysis for ANCOVA, alpha = 0.05 and power = 0.8. As this was a pilot study without a prior comparable study, an moderate effect size was used ( $f=0.35$ ). All the parameters used to calculate the sample size are summarised in table 9.2. A visual representation of the power calculation is provided in figure 9.3.

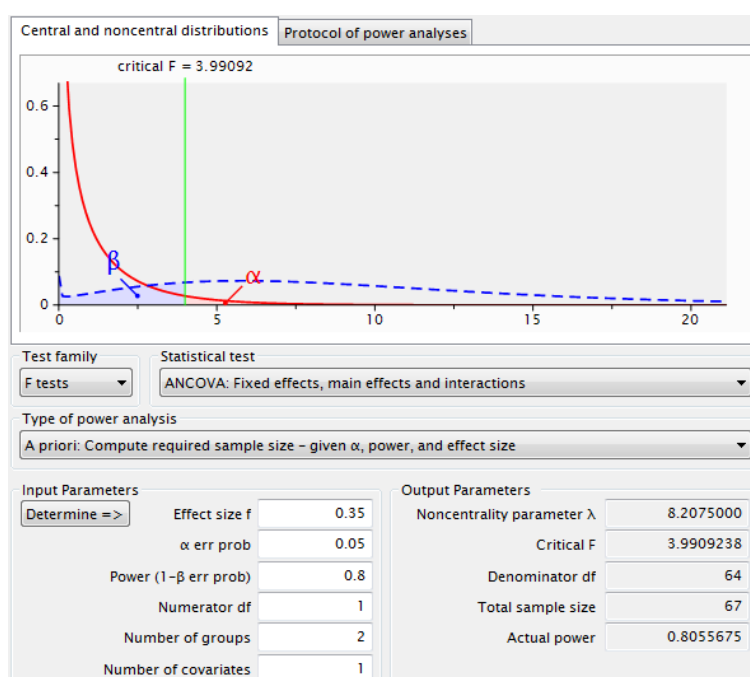


Figure 9.3: Power calculation performed with the GPower software.

Post-hoc analysis using GPower with the actual sample (61) and effect size (Cohen's  $d=0.02$ ) showed that the study's achieved power (0.05) was insufficient to either



Statistical test	ANCOVA: Fixed effects, main effects and interaction
Test family	f-test
Type of power analysis	A priori
Effect size f	0.35*
Alfa err prob	0.05
Power (1-beta err prob)	0.8
Numerator df	1
Number of groups	2
Number of covariates	1

Table 9.2: Parameters used to calculate required sample size with the GPower software.

\* Denotes a moderate effect size and is an estimated due to lack of existing comparable studies.

confirm or refute H1 with confidence. Reasons for this are offered in the discussion.

### 9.2.5 Inclusion criteria

Participants were required to meet the following criteria to participate:

1. Working at one of three hospitals selected to be included in the study.
2. Completed module one of the Learn Blood Transfusion (LBT) e-learning program between 1 January 2014 and 1 September 2014.
3. Registered in the LBT database as either doctor, registered nurse or midwife, or as a hospital blood bank staff (e.g. biomedical scientist).
4. Registered in the LBT database with a professional email address (such as nhs.scot.uk or nhs.net), rather than a personal email account (such as hotmail, gmail, etc).

## 9.3 Results

Despite extending the study deadline, the recruitment target sample size (68) was not reached and only 61 practitioners participated (estimated 13% response rate). Of these, 29 were randomly allocated to the SBC app and 32 to the guidelines control group. The two groups were well-balanced (see table 9.3 and 9.4).

Mean scores at pre-test were 32% ( $M=2.59$ ,  $SD=1.90$ ) in the app group and 34% ( $M=2.72$ ,  $SD=1.97$ ) in the control. Scores increased significantly at post-test to 58% ( $M=4.66$ ;  $SD=2.07$ ;  $t(28)=4.69$ ;  $p<0.01$ ;  $95.CI=1.17-2.97$ ) and 61% ( $M=4.84$ ;  $SD=2.14$ ;  $t(31)=6.28$ ;  $p<0.01$ ;  $95.CI=1.44-2.81$ ) respectively. Between-group differences in learning gain was negligible ( $d=-0.0261$ ;  $95.CI=-0.5287-0.4764$ ). However, the acceptability of the app was rated significantly higher (median [IQR]: 75 [75-88] vs 69 [50-75]; Mann-Whitney  $U=693.5$ ;  $p<0.001$ ; median difference in location: 13.3;  $95.CI=6.67-26.7$ ). The test scores statistics are summarised in table 9.5 and the qualitative feedback on the SBC app and guidelines is reported as part of the discussion.

50 participants (82%) completed the study on a desktop or laptop computer, 8 (13%) completed it on a smartphone and only 3 (5%) used a tablet. In terms of the web browsers used to complete the study, Internet Explorer (IE) 8 was used by 34 (56%), Safari by 13 (21%), Chrome by 8 (13%) and Firefox by 3 (5%). Two respondents (both in the app group) used Internet Explorer 6 and 7. Neither reported any issues even though it is 10 to 15 years since these browsers were first released.

Table 9.3: Respondent demographics by group allocation.

	App (n=29)	Guidelines (n=32)
<i>Age group</i>		
60 and over	0	2
50-59	5	7
40-49	4	6
30-39	6	8
20-29	13	8
Not answered	1	1
<i>Position</i>		
Consultant	3	6
Specialty Registrar	2	1
Specialty Trainee Registrar	3	2
Foundation Doctor (any year)	12	8
Nurse	6	10
Biomedical Scientist	2	3
Other	1	2
<i>Specialty</i>		
Anaesthetics or Theatre	2	8
Accidents or Trauma	3	1
Bloodbank, Haematology or Oncology	5	5
General Medicine	5	5
Obstetrics, Neonatology or Paediatrics	1	2
Surgery (any type)	4	4
Other	8	7
Not answered	1	0
<i>If you use a smartphone or tablet device, where do you use it?</i>		
At home and at work.	21	15
At home only.	6	14
I do not use a smartphone or tablet.	1	2
Not answered	1	1
<i>Have you used apps in your education or practice before?</i>		
Yes, in both.	15	14
Yes, in education only.	3	3
Yes, in practice only.	0	2
No, in neither.	9	13
Not answered	2	0

Table 9.4: Respondents' medical experience, familiarity with special requirements and self-rated confidence in the indications for special blood components by group allocation.

	App (n=29)	Guidelines (n=32)
<i>How many years of medical experience do you have?</i>		
30 or more	3	2
20 to 29	3	6
10 to 19	6	11
1 to 9	6	5
Less than 1	11	8
<i>Service in workplace with patients who have special requirements. *</i>		
Over 36 months, in current workplace	8	14
13-24 months, in current workplace	2	1
4-6 months, in current workplace	2	1
1-3 months, in current workplace	2	2
13-24 months, in past workplace	2	1
4-6 months, in past workplace	2	0
No exposure to this patient group	11	13
<i>How often do you work with patients who have special requirements?</i>		
Every day	3	2
Every other day	1	1
Every week	1	1
Every other week	0	1
Every quarter	2	0
Every six months	0	1
Less frequently than every six months	13	14
Never	5	5
Don't know	4	7
<i>How confident do you feel about the indications for special blood components? **</i>		
Very confident	1	1
Confident	7	5
Neither confident nor unconfident	8	3
Unconfident	10	18
Very unconfident	3	4
Don't know	0	1

\* Composite of two conditional questions: "Does your current place of work have patients who require CMV-negative or irradiated blood components, and if so how long have you been with your current workplace?"; and "Have you previously been part of a workplace with patients who require CMV-negative or irradiated blood components, and if so how long did you work there?"

\*\* Confidence was measured prior to knowledge tests.

Table 9.5: Means scores at the pre- and post knowledge tests, with standard deviation and effect sizes (Cohen's d).

	App (n=29)	Guidelines (n=32)
	<i>Test score means (sd)</i>	
Baseline	2.59 (1.90)	2.72 (1.97)
Follow-up	4.66 (2.07)	4.84 (2.14)
Change	2.07 (2.37)	2.12 (1.91)
	<i>Within group effect size 95% (CI)</i>	
Cohen's d	1	2
95% CI	1 to 2	1 to 2
	<i>Between groups effect size (95% CI)</i>	
Cohen's d	-0.0261 (-0.5287 to 0.4764)	

## 9.4 Discussion

As can be seen in tables 9.3 and 9.4, participants in the app group were somewhat younger (66% were below age 40 compared to 52% in the control group), had fewer years of medical experience (median 4 vs. 11.5) and held less senior positions.

However, the groups were well-balanced in terms of smartphone and mobile app use, baseline knowledge, spread of medical specialties, confidence about the clinical indications and frequency of working with patients who have special requirements.

A majority of participants (48/61) did not work with this patient group on a biannual or more frequent basis. About one third (21/61) reported having never worked with such patients or were unsure if they ever had. Consequently, most participants

(35/61) felt unconfident about the indications for irradiated and CMV-negative blood.

These results reflect the heterogeneity of staff involved in blood transfusion as captured by the Learn Blood Transfusion database. The sampled population thus extended beyond the specialties which are likely to have the most experience of patients with special requirements, such as haematology, oncology, neonatology, obstetrics and blood banking.

Furthermore, nearly two-thirds (37/61) reported having used apps in either their education or practice previously, which is similar to prior surveys of mobile app use among healthcare practitioners (Mobasher et al., 2015; O'Reilly et al., 2014; Carter et al., 2014; Payne et al., 2012; Franko and Tirrell, 2012).

#### 9.4.1 Efficacy of the SBC app

Both groups nearly doubled scores on the post-test compared to pre-test. Mean scores at pre-test were quite low with only 32% ( $M=2.59$ ,  $SD=1.90$ ) correct answers in the app group and 34% ( $M=2.72$ ,  $SD=1.97$ ) in the control group. The scores increased significantly at post-test to 58% correct ( $M=4.66$ ;  $SD=2.07$ ;  $t(28) = 4.69$ ;  $p<0.01$ ;  $95.CI=1.17-2.97$ ) in the app group and 61% ( $M=4.84$ ;  $SD=2.14$ ;  $t(31)=6.28$ ;  $p<0.01$ ;  $95.CI=1.44-2.81$ ) in the control.

Analysis of the questionnaire suggested that the questions were balanced (correct answer percentage:  $M=46.2$ ;  $SD=18.4$ ;  $range=25-85.2$ ) and discriminated performance

well (point-biserial correlation:  $M=0.34$ ;  $SD=0.09$ ;  $range=0.17-0.54$ ) (Varma no year, 6). However, as can be seen from the large standard deviations in the scores, there was considerable variation in the performance of members within each group. This contributed to a much smaller than hypothesised between-group effect size ( $d=-0.02$ ;  $95.CI=-0.5287-0.4764$ ). Coupled with the small sample size, this resulted in insufficient power to refute or confirm whether the app or guidelines is more effective (H1). As discussed above, variations in participants' prior experience of patients with special requirements contributed to the variation.

#### 9.4.2 Post hoc analysis

Post hoc analysis sought to identify and compensate for sources of variation. A moderate correlation ( $r^2=0.4$ ) between follow-up score and the time spent exploring the app or guidelines, and then answering the follow-up questions, was noted up to about ten minutes. Using more than ten minutes to explore the guidelines and app, and completing the follow-up questions, was not associated with an improvement in score.

Overall scores were also significantly affected by a small number of participants who clicked through the evaluation without studying the app or guidelines. For example, two participants who spent less than two minutes reviewing the app and answering the eight follow-up questions, went from a score of four on the baseline to zero and one on the follow-up test.

When excluding participants who had very short completion times, presumably due to random guessing, the app group performed better than the guidelines group (Cohen's  $d=0.15$ ). However, even at this effect size, the sample size was too small to rule out a type I error.

When designing the evaluation, I considered forcing all participants to spend a minimum amount of time studying the app or guidelines before they could proceed to the remaining questions. However, I decided against this because it could cause frustration and unnecessary stress, particularly since many participants would be completing the study at their workplace.

In retrospect, putting some boundaries on the interaction time with the app and guidelines could perhaps have improved the quality of the collected data and reduced some of the variability arising from the time participants chose to spend in reviewing the app and guidelines.

Another important source of variability was participants' medical specialty. Biomedical scientists and haematology staff performed significantly better than participants from other specialties where blood transfusion and patients with special transfusion requirements are less likely to be encountered. The groups were reasonably well-balanced in this regard because the final sample reflected the stratified randomisation strategy.



### 9.4.3 Acceptability of the SBC app

The SBC app was rated significantly more positive on all of the four acceptability dimensions (ease of finding information, enjoyment of use, intent to reuse and likelihood to recommend) compared to the guidelines (fig. 9.4). The aggregate acceptability index (range 0-100) was significantly higher for the app (median [IQR]: 75 [75-88]) vs 69 [50-75]; Mann-Whitney  $U=693.5$ ;  $n_1=29$ ,  $n_2=32$ ;  $p<0.001$ ; median difference in location: 13.3; 95.CI=6.67-26.7).

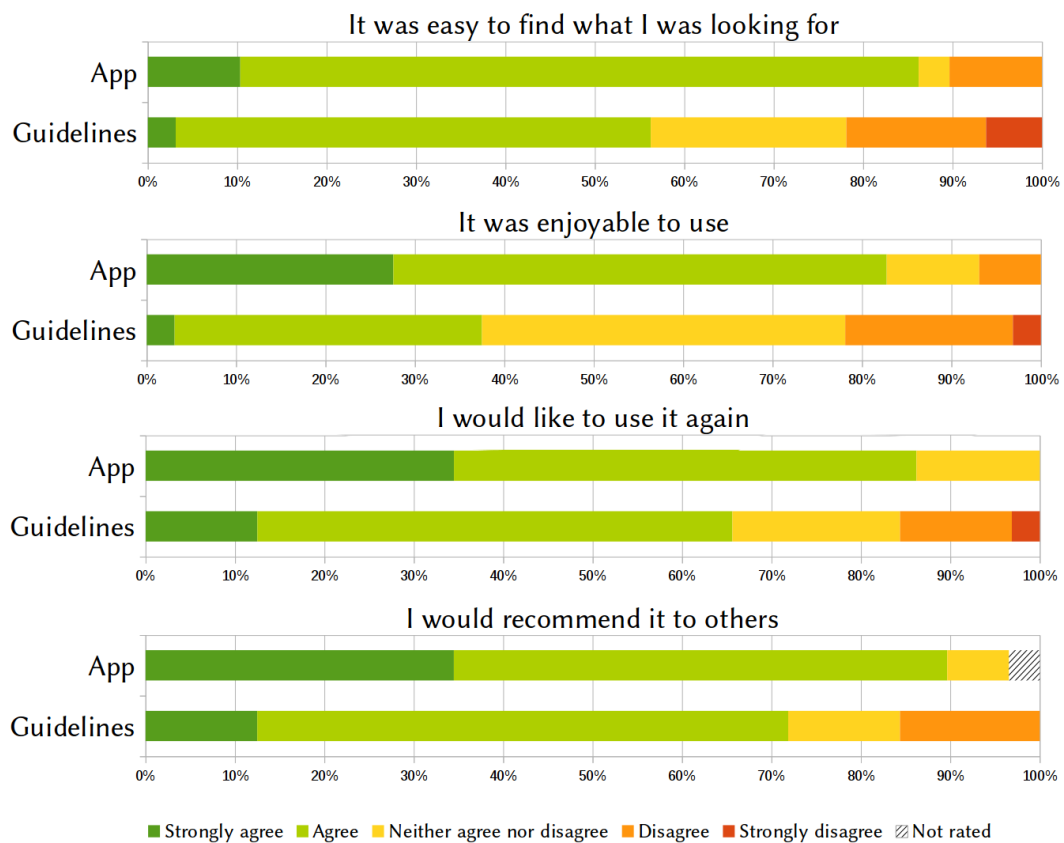


Figure 9.4: Ratings of the revised SBC app and existing local hospital guidelines. Base: All 61 participants.

The comments offered by participants shed light on this result. Ten participants provided wholly positive comments relating to the SBC app. Utility and relevance to current or future work responsibilities were among the most frequently praised aspects of the app:

“It is a good reference for people who are taking part in transfusion. [...] I would buy it to have on my phone as a reference.” (Nurse, 30-39, Haematology)

“Don’t use bloods with special requirements much [...] but this app would be extremely beneficial for future roles, especially oncology.” (FY1, 20-29, General Surgery)

In particular, its function as a cognitive aid offering access to information that is required sporadically and difficult to memorise was emphasised:

“Having an app reference for this is very useful, as I don’t need to prescribe these products often. So I have no means to build up experience, and would always worry that I’m forgetting about a key indication.” (Foundation Year 1 [FY1] Doctor, 30-39, Plastic Surgery).

Several participants commented that the app was easy to use and contained clear and interesting information worthy of further study. For instance:

“Easy to use, short statements that make rationale for indication clear. May take more than one read to cement all knowledge but this is achievable in short time frame so not a daunting task.” (Specialty Trainee Registrar, 30-39, Anaesthesiology)

“Easy to follow and information interesting. I now want to go back when I have more time and look at the information. Definitely need to know more about this.” (Nurse, 40-49, General Medicine)

However, one participant struggled to understand and find answers to some of the questions, and felt that a “simple list of conditions” would have been easier to use.

Another participant experienced a technical problem that caused the app to freeze. As this was the only report and no details were provided, it is difficult to determine the cause of the issue.

The remaining comments about the SBC app expressed a mix of positive and negative sentiments, often together with constructive feedback. Three participants felt the user experience could be further improved:

“Very informative, could be easier to navigate though, with more headings” (Nurse, 30-39, Haematology).

Furthermore, two participants felt that there was a large amount of information that could perhaps be presented better:

“A lot of information in the app. Perhaps could be simplified [...] a simple pathway could be used, with the option to then read/access more detail.” (FY1, 20-29, General Medicine)

Others felt that the app’s use of traffic light icons would benefit from an explicit explanation (green: no special blood required; amber: special blood may be required; red: special blood required). In contrast, only one participant left detailed positive feedback in relation to the guidelines:

“The guidelines were clear and concise with not too much jargon which would require too high a level of medical knowledge for our role. Anyone in Blood Sciences should be able to follow these guidelines without difficulty.” (Blood bank/Hospital lab staff, 30-39, Haematology)

Another three participants felt that the extensive use of bullet points in the guidelines made it easy to find information quickly. However, an equal number commented that the guidelines contained too much information and that it was difficult to use:

“The guideline is incredibly wordy! Trying to read through it to identify the correct information is a painful process.” (Consultant, 40-49, Anaesthesiology)

Several participants suggested ways in which the guidelines could be improved and suggested using techniques such as colour-coding, a tabular format, re-organising by medical condition and subdividing information into more manageable chunks. Furthermore, an explanation of the rationale for irradiated and CMV-negative blood components was requested;

“It would be helpful at the start of the section to clearly state what is achieved by irradiation and a little more explanation of the reasons for this. Otherwise it will be difficult to retain this info. In the CMV section, again a reason why CMV negative blood should be used in these specific instances, as this has changed a bit over the years.” (Consultant, 50-59, Anaesthesiology)

#### **9.4.4 Limitations and lessons learned**

This study has several limitations related to overall research design, choice of control treatment, methods of assessing clinician knowledge and sample size. In pre-post testing it is difficult to rule out that measured effects are not a side effect of the research design (so called learning or practice effects) rather than the intervention being tested.

It was to reduce this confounding effect that all questions were unique and randomised, and answer feedback was withheld from participants. Ultimately, a solomon

four group design could have enabled the effect of simply answering the questionnaire on test scores to be factored out. However, it would have required a much larger sample size and was not feasible for this reason.

On the topic of sample size, the response rate was slightly lower than anticipated and this is likely due to the timing of the study coinciding with the Christmas period and survey fatigue. It is possible that alternative recruitment methods, such as a postal invitations, would have enticed additional participants. In retrospect, it is clear that the study was underpowered as the difference in effect size between the two groups was much smaller than theorised. Reasons for this has been explored above, but are likely due to heterogeneity in respondents. Future studies may achieve greater statistical power by targeting a more homogenous subgroup, such as biomedical scientists.

Other limitations of the study pertain to the suitability of the control treatment (hospital guidelines). While they represent current practice, the guidelines differed in length compared to the app by a factor of ten. This meant that the required time to review the app could differ significantly from the guidelines. As discussed above, this was not something that was easily compensated for in this research design, although controlling for time retrospectively helped identify and quantify this issue.

One can question the validity of a short multiple-choice quiz as an adequate measure of knowledge. As discussed at the start of the chapter, there are different kinds of knowledges and different ways of measuring them. A more comprehensive study

would aim to capture a broader spectrum of knowledges using a combination of quantitative and qualitative methods. However, this was beyond the scope of the current study. Additionally, I had originally hoped to assess, by means of a follow-up survey scheduled, whether participants retained newly gained knowledge over time. Unfortunately, due to the low response rate and the small number of respondents who agreed to participate in a follow-up survey it was not feasible.

## 9.5 Conclusion

This study is among the first to evaluate a mobile learning app targeting practitioners in transfusion medicine. The results confirmed low levels of existing knowledge and confidence of the correct use of irradiated and CMV-negative blood components among healthcare staff. As participants had completed e-learning on safe transfusion practice within the last 12 months, the result raises questions about the effectiveness of current training programmes.

Performance on the follow-up test significantly improved from baseline in both groups, suggesting that the guidelines and SBC app could be effective ways of enhancing practitioner knowledge. The study was not powered to detect a statistical difference in superiority of either intervention. Reasons for this are likely to include heterogeneity among research participants and variation in the time invested by participants in completing the questions.

That said, the SBC app was rated considerably more positively than the local hospital guidelines, suggesting it has potential to be more widely adopted. As there is a shortage of existing learning interventions addressing this topic, the SBC app could complement existing blood transfusion education initiatives. Further research is, however, required to assess the impact on clinical outcomes and knowledge retention over time.

## **Part III**

# **SYNTHESIS**





# **Chapter 10: Discussion**

This chapter discusses the findings from the literature and the empirical work. I begin by summarising the aims and objectives, and key findings from prior work. The main results and limitations of the thesis are then discussed, including the outputs of the collaborative project. I then discuss the implications of the findings and relate them to prior work. Finally, I conclude by highlighting the contributions to knowledge and offering recommendations for practice.

## **10.1 Research aim and related work**

The purpose of the thesis was to explore how the quality and credibility of medical apps for healthcare practitioners could be improved by adopting a collaborative approach to app design and evaluation. To achieve this, I initiated a project where I worked with practitioners in transfusion medicine to create and evaluate a mobile learning app to improve the care of patients with special transfusion requirements. To inform the project, I reviewed prior work related to the adoption, design and evaluation of medical apps, and literature examining transfusion medicine practice in the UK.

### **10.1.1 Prior work in eHealth and related fields**

The review identified five key findings that were relevant to the project. Firstly, mobile apps are increasingly used by healthcare practitioners in both their medical education and clinical practice. However, barring a few notable exceptions, there is a shortage of published evidence for the effectiveness of many medical apps.

Secondly, several studies have identified significant shortcomings in a large number of available apps covering a wide range of medical specialties, and in apps intended for both patients and healthcare practitioners. The causes of these limitations have rarely been carefully examined in the literature. However, weaknesses in design, a lack of input from medical professionals and inadequate evaluation have been suggested as possible causes.

Thirdly, prior work in eHealth and related fields draw attention to the importance of evaluation research to understand the impact of healthcare information technologies on a variety of outcomes. Fourthly, embedding healthcare information technologies into existing work practices and organisational processes have been highlighted by several scholars as critical for the successful uptake of such interventions. Depending on the type of system, significant implementation effort may be required to achieve this.

Finally, previous attempts at assuring the quality of medical apps have met with limited success. For example, notable third party intermediaries, such as the NHS Health Apps Library and Happtique, have failed to review apps in a transparent, effective and timely fashion. Similarly, the vast majority of medical apps fall outside the remit of regulators. Thus, addressing this problem requires another approach. One method is to develop mechanisms that encourage healthcare practitioners to participate actively in the design and evaluation of medical apps. However, there are as yet few examples where this strategy has been successfully demonstrated.

### **10.1.2 Prior work in transfusion medicine**

The review of the composition, manufacture and use of blood components provided a further foundation for the research project. It identified four key points. Firstly, blood transfusion practice takes place in a complex socio-technical system involving many

actors with specialised knowledges. Thus, changing existing practices is not trivial and requires interventions at several levels.

Secondly, the management of blood transfusion risks is an ongoing challenge as the scientific basis evolves. It requires careful consideration of all parts of the transfusion chain, from blood donor recruitment through to patient monitoring.

Thirdly, work by Serious Hazards of Transfusion (SHOT) have identified that the use of “special blood components” is a challenging area where mistakes occur. SHOT have recommended that practitioners’ knowledge of the correct use of irradiated and cytomegalovirus-negative blood components should be improved to prevent mistakes.

Finally, there is a shortage of learning resources addressing this topic in detail. This finding became the starting point of the collaborative action research project and the resulting Special Blood Components (SBC) mobile learning app.

## **10.2 Findings from the empirical work**

The five empirical studies shed light on a wide range of issues related to how the quality and credibility of medical apps might be improved by adopting collaborative design and evaluation methods. In this section, I will briefly discuss the findings and limitations of each study.

### **10.2.1 Study 1: review of an existing app**

The objective of this study was to review an existing blood transfusion app targeting healthcare practitioners in order to learn from what has gone before. The study, among the first independent reviews of an app in transfusion medicine, revealed notable weaknesses in the clinical content, dose calculator and usability of the NHSBT Platelets app. The findings highlight how medical apps released with bugs and usability problems are not only likely to be rejected by practitioners, but could potentially also contribute to medical errors.

In particular, the platelet dose calculator does not check for input errors. Instead of failing, it will recommend a standard dose of platelets. This software bug, which has remained unfixed since the app was published, could lead clinicians to over-transfuse patients. It in turn can lead to risks such transfusion-associated circulatory overload (TACO).

### **10.2.2 Study 2: concept validation of the proposed app**

The purpose of this study was to gauge the extent to which an app could be an acceptable intervention for improving the use of irradiated and CMV-negative blood components. It also aimed to examine the assumptions underpinning the proposed Special Blood Components app and solicit early feedback on the initial working prototype from practitioners.

Interviewing participants from different hospitals, specialties, and with different professional responsibilities and priorities, deepened my understanding of the problem that the SBC app sought to address. This included the challenge of providing continuity of care given variations in information systems and processes between hospitals.

A limitation of this study was that it only captured the views of a small number of practitioners. However, it was sufficient to observe differences and similarities in how practitioners from different medical specialities defined and analysed the problem, and the emphasis they placed on potential interventions. This early feedback was essential for developing a better understanding of the problem, for identifying inaccuracies in the prototype data model, for improving the usability, and refining the purpose and audience of the app.

Moreover, the practitioners were enthusiastic and generous with their time. It was not difficult to recruit them because access was brokered through the Scottish National Blood Transfusion Service (SNBTS). Establishing an effective feedback loop would encourage the participants to remain engaged in the project, since they would be able to see the effect of their feedback. However, I found that it is was difficult to incorporate and communicate changes back to participants in a timely way. An important reason for this was the lack of good collaborative development tools.

### 10.2.3 Study 3: collaborative app design with the WAE

To facilitate the collaborative working on the SBC app, I created the Web App Editor (WAE). It is a browser-based authoring tool that allow multiple users to collaborative during the development of web apps. The current version supports code highlighting and syntax checking, multi-file editing, web hosting and easy preview of work in progress on desktop and mobile devices, version control and file management.

In this study, I discussed the design and testing of the the Web App Editor with students in two certified introductory courses on mobile app development, and in a Masters project aiming to create an app to elicit symptoms of stroke patients.

In these contexts, the WAE enabled users with little prior experience to learn about, create and test mobile apps. These results show that it is possible to collaborate with beginners at the level of code. This is a departure from how medical apps projects are often approached, but an extension of the participatory method used to design and evaluate the SBC app. The approach is informed by user innovation theory and extends studies where medical students and junior doctors experiment with creating medical apps (Masters, 2014; Subhi et al., 2014).

### 10.2.4 Study 4: usability evaluation of the SBC app

The purpose of this study was to evaluate the usability and content of the second revision of the Special Blood Components (SBC) app, and to identify further improvements



to it. 54 medical students identified weaknesses in the content, usability and learning quiz which required additional work to address.

Despite these limitations, the app was rated acceptably on the system usability scale. However, an important limitation in this study was that most of the students lacked experience of participating in blood transfusions. It is possible that respondents with greater experience would have been able to more critically evaluate the app.

Additionally, the use of a remote evaluation survey exceeded expectations as the collected data was quite rich and insightful. The flexibility of evaluating medical apps online opens up opportunities to more easily integrate formative evaluation into the app development process

### **10.2.5 Study 5: randomised controlled pilot of the SBC app**

This study aimed to evaluate the efficacy and acceptability of the SBC app with healthcare practitioners involved in blood transfusion. To conduct the study, I created the Web App Trial (WAT) system. It is an application for conducting online randomised controlled trials of web apps.

The study confirmed low levels of existing knowledge of the correct use of irradiated and CMV-negative blood components among healthcare staff as reported by SHOT. As participants had completed e-learning on safe transfusion practice within the last 12 months, the result raises questions about the effectiveness of current train-

ing.

Follow-up knowledge test scores significantly improved from baseline, suggesting that the SBC app could be an effective way of enhancing clinicians' knowledge. However, the study was not powered to detect a statistical difference in the magnitude of performance change between the app and local hospital guidelines (control intervention). Furthermore, the SBC app was rated considerably more positively than the control, suggesting it has potential to be more widely adopted. More research is required to assess the impact on clinical outcomes and knowledge retention over time.

Additionally, the study provides a validated knowledge test and a benchmark dataset that is valuable to future research and audits of healthcare practitioners' understanding of special blood components. The results could also inform the development of blood transfusion e-learning materials that are increasingly accessed on mobile devices in both medical educational and practice contexts. Finally, the study demonstrated the feasibility of conducting controlled evaluations of medical apps using an entirely web-based system. This is an area that should be explored further as there is a need to develop methods that enable rigorous and cost-effective evaluations of medical apps.

### **10.3 Discussion**

Published apps related to transfusion medicine and other medical specialties have several limitations. Some limitations could be considered so serious that the apps are

unsafe to use (yet fall outside the remit of regulators). It is not only apps by “rogue developers”, hoping to scam gullible patients, that are problematic. Apps promoted by recognised medical bodies and intended for healthcare practitioner can also be affected by serious limitations.

I argue that attempts at tackling this problem would benefit from adopting an integrated approach that considers the whole life-cycle of medical apps and the socio-technical context in which they are produced. Concentrating efforts to a single stage of the archetypal software life-cycle, such as design, testing, evaluation, implementation or maintenance is likely to be an unsatisfactory strategy. The implementation, evaluation and design of healthcare systems are deeply interwoven activities that demand high levels of participation by healthcare practitioners (Granlien, 2010).

Furthermore, successful technology projects demand that users are innovative during system implementation to resolve issues at the point of use (Fleck, 1994). That is to say, design is not an upfront activity. Rather it continues throughout the project life. With this more nuanced view of the innovation process, the quality and credibility of medical apps could be regarded as emergent properties of the complete life-cycle of the project.

To give a concrete example, although the brunt of the empirical work concerns the design and evaluation stages (a reflection of the PhD timeline), it became clear over the course of the project that the quality and credibility of medical apps depend just

as much on appropriate software testing, implementation planning and active maintenance after launch. These in turn are conditioned on a combination of technical and social aspects, such as the choice of technical architecture, organisational capacity, commissioning practices, budgeting and mindset.

So, what form should a holistic approach to improving medical apps take? Research on medical apps is underdeveloped (Lupton, 2014, p.618), but can nonetheless inform strategies. For instance, inadequate involvement of healthcare professionals in medical app projects has been identified as a cause of deficiencies by several authors (Masters, 2014; Visvanathan et al., 2012; Hamilton and Brady, 2012; Haffey et al., 2013b; O’neill and Brady, 2012; Zhou et al., 2012). This is an astute observation as effective interdisciplinary collaboration throughout healthcare information technology (or “eHealth”) projects is critical to create quality interventions that are supported by strong evidence (Pagliari, 2007).

Furthermore, studies of other kinds of eHealth interventions, such as electronic healthcare records, are informative. For example, a systematic review of eHealth studies published between 1997 and 2010 concluded that the presumed benefits of many eHealth interventions have not been demonstrated empirically (Black et al., 2011).

This finding stems in part from a widespread and erroneous belief that the presumed impacts of eHealth interventions are self-evident and do not warrant investigation (Car et al., 2008, 386). When evaluations were available, Car et al. (2008, 387-389)

found that the robustness and validity of the findings were severely limited by issues such as inappropriate research design, unclear outcome measures and failure to assess long-term impacts.

### **10.3.1 Challenges of evaluating medical apps**

There is an urgent need to develop better methods to quality-assure medical apps, most of which fall outside the remit of regulators. The task of regulating mobile medical apps on the market through centralised bodies, such as the US FDA or the MHRA in the UK, is challenging due to the large number of health apps. Top-down central regulation is inadequate and quality assurance efforts have to come from intermediaries and the “grass roots”.

Evaluating the effectiveness of healthcare technology can be very challenging and is rarely undertaken. With the exception of a small number of apps, most apps appear to be developed without a clear research agenda to investigate and evidence their effectiveness, and lack associated peer-reviewed publications. Formal evaluations of apps are important to give them credibility.

However, rigorous evaluations are resource-intensive and may detract from the resources available to make practical improvements to an app. For this reasons, it is important to develop scalable evaluation strategies that can make the evaluate-improve cycle fast and effective. The Web App Trial system, used in study five, attempts to strike

this balance between research rigour and flexibility. However, improving this situation requires more than tools.

### 10.3.2 Role of interdisciplinary collaboration

Improving the quality and credibility of medical apps require that app developers, medical experts, potential users and other stakeholders collaborate effectively. This was evident from previous work on the design and evaluation of eHealth interventions (Pagliari, 2007), as well as studies drawing attention to the lack of participation of healthcare practitioner in the design of medical apps (Masters, 2014; Visvanathan et al., 2012; Hamilton and Brady, 2012; Haffey et al., 2013b; O’neill and Brady, 2012; Zhou et al., 2012).

These findings from the literature were readily confirmed in the empirical studies. For example, in the review the NHSBT Platelets app, reported in the first study, important shortcomings in the clinical content, user interface design and the platelet dose calculator were identified. These findings suggest that the app had been designed without sufficient involvement of healthcare practitioners who were target audience for the app.

Furthermore, the design and evaluation of the Special Blood Components (SBC) app, reported in studies two, four and five would not be possible without the generous cooperation of many medical practitioners and students. Indeed, over the course of

project, more than one hundred individuals contributed to the SBC app. Two striking examples of the importance of this interdisciplinary collaboration are illustrated in study two and four, where participants challenged key assumptions of the SBC app.

### **10.3.3 Need for collaborative tools and training**

As highlighted in study two and three, collaborations involving medical apps are made difficult by the lack of good tools that enable effective collaborative practices. In order to be responsive to the needs of users, the design process has to be iterative and flexible. This is one of the guiding principles of “agile” software development methodologies. Minimising the friction, time and effort required to solicit feedback from user, make the required changes and feed the results back to user can make a considerable impact on the rate of quality improvement.

Developing such a process of continuous improvement was challenging. The Web App Editor (WAE) is a system supporting collaborative development of apps. The WAE editing environment simplifies the development process and lowers the barriers to collaborate on apps. It achieves this by removing dependency on special software or hardware, providing direct access to source code and a live preview of the app. Integration with the Git distributed versioning system allows a history of changes made by any number of contributors.

The editor is relevant to current research exploring teaching initiatives where med-

ical students and healthcare professionals learn about and develop medical apps (Youn and Wiechmann, 2015; Masters, 2014). A good way to learn is by studying the work of others. Unfortunately, this is difficult as at the moment many medical apps are developed proprietary software, leaving users to rate and comment in app stores, rather than to inspect the code and contribute to them directly. Moreover, for users of medical apps, appreciating how they work and have been created can inform judgement on whether to use an app or not. By exposing the inner workings of apps, it is also easier for evaluators to examine the correctness and reliability of an app.

Thus, making apps open source have potential to encourage wider participation in their development, evaluation and maintenance, as well as leading to new apps re-using previous code. There are collaborative platforms, such as Github.com, where it is possible to cooperate effectively on software code. However, there is a lack of awareness and uptake experience of these tools outside of less technical communities. There is therefore a need to support the acquisition of knowledge and skills among interested healthcare practitioners.

## 10.4 Conclusion

The results of the review in chapter two suggest that apps spanning a wide range of specialties may suffer from important shortcomings and their use could be detrimental to patient safety. Mitigating these risks is not trivial and requires multiple interven-



tions. Attempts at top-down regulation of medical apps have met with limited success as the majority of medical apps fall outside the remit of regulators. Indeed, some of the most publicised examples of apps that have been withdrawn from the market originate from consumer protection agencies targeting consumer-oriented apps which make misleading marketing claims, rather than from the bodies that regulate medical device safety.

Repeated calls from scholars and medical professionals for a “certified selection” or “white-list” of trusted medical apps also look increasingly unlikely to gain traction. Notable initiatives, such as the defunct NHS “Health Apps Library” and Happtique, which both intended to offer comprehensive app certification programmes, have failed to review apps in a transparent, effective and timely fashion.

A more promising approach is to invest in training to enable healthcare practitioner to manage the opportunities and perils of (untested) medical apps. The notion of an “eHealth literacy” (or “medical app literacy”) is pertinent as practitioners retain responsibility to patients and must exercise caution whether they rely on a paper-based medical guideline or an “appified” version. Although some medical schools have encouraged their students to learn about and create apps, other educational programmes may be failing to provide students with the necessary IT skills and knowledge.

A novel way to attempt to tackle this issue is to develop mechanisms that encourage healthcare practitioners to participate actively in the design and evaluation of medical

apps. Failure to involve healthcare practitioners in the development process, together with a general lack of medical app evaluation research, are among the most frequently cited causes of deficiencies in apps. Thus, there is a need for collaborative app design and evaluation research across professional boundaries.

The open source and open science movements could offer lessons for such an endeavor. These seek to promote increased transparency and openness in software development and medical research by opening up access to computer code and research data, including data from clinical trials. These approaches could potentially make it easier to inspect how apps work, and to assess their correctness. However, there are as yet few examples where this strategy has been successfully used. Apart from a small number of counter-examples, political and cultural barriers, such as entrenched power structures, have previously impeded these approaches in medicine.

Additionally, it is critical to develop a more integrated approach to app development that incorporates iterative design with evaluation research. Perspectives from user-centered design, co-design, user innovation and evaluation research are valuable in furthering this agenda. As are insights from the social studies of technology and innovation that suggest that design, implementation and innovation should be understood as interleaving processes. Thus, simple linear models of the software life-cycle are misleading and brush over the potential for innovations by users. Additionally, there is a need to develop appropriate app evaluation methods that strike a balance

between validity, reliability, cost and rigour, and which generates data that can be used to improve the quality and credibility of apps.

To summarise, the growing adoption of apps by practitioners raise questions about the extent to which medical apps are safe to use and how one would determine this. It also raises questions about how development and evaluation processes should be carried out to ensure medical apps are “fit for purpose”. There is little research evidence to answer these questions with confidence.

The thesis contributes to knowledge by offering a critical and reflexive (Finlay, 2002) analysis of the research, design, engineering and socio-technical (c.f. Hughes, 1987) challenges of developing and evaluating medical apps for and with healthcare practitioners. I have argued throughout the thesis that concerns related to the lacking quality and credibility of many medical apps cannot be effectively addressed by “market forces” (such as consumer behaviour on app stores), “vetting” by trusted third parties or top-down regulation by governmental bodies with relatively limited resources.

Rather, these issues are symptoms of limitations in the current app commissioning, development and evaluation practices. Drawing on prior work, and using the SBC app as example of how healthcare practitioners, medical students and others contributed quality improvements and helped evidence its usability and efficacy, I suggest that these issues could be overcome by development strategies that promote on-going interdisciplinary teamwork.

Dedicated collaborative app design and evaluation tools, such as the WAE and WAT, can facilitate such strategies, but are still in their infancy. It is also critical to develop and reward the digital skills of healthcare practitioners so that they can become critical consumers of apps and can actively shape the information technologies that they are increasingly reliant on.

This thesis has furthered understanding of the adoption, design and evaluation of medical apps by healthcare practitioners. On the basis of these five studies, I argue that the design and evaluation of high quality medical apps supported by evidence requires specialised knowledges and skills. Close collaboration between medical domain experts, software developers/designers, healthcare technology evaluators and other stakeholders is therefore critical to improve the quality and credibility of medical apps.

In conclusion, creating high quality medical apps that are supported by evidence is a considerable undertaking and depends on a mix of knowledges and skills. It requires that healthcare practitioners, software developers and others work together effectively. Hence, the WAE and WAT are key research outcomes. They enabled participants to contribute improvements and assess the usability and efficacy of the SBC app. The results suggest that the SBC app is easy to use and can improve practitioner knowledge. Further work remains to pilot and evaluate the SBC app in a hospital setting.

### **10.4.1 Implications for transfusion medicine**

In terms of improving the correct use of irradiated and CMV-negative blood components, the thesis confirms earlier work that identify gaps in the knowledge among healthcare practitioners. Thus, it reaffirms the importance to follow SHOT recommendations to improve training in this area.

The Special Blood Components (SBC) app is the result of collaboration with over one hundred doctors, nurses, medical students and others. It can promote the correct use of irradiated and CMV-negative blood components by providing practitioners with easy access to learning materials and clinical indications. The usability, efficacy and acceptability of the app have been demonstrated in the evaluation studies reported in the thesis.

For example, evaluations with medical students and practitioners suggest that the SBC app is an attractive, efficacious and easy to use intervention that could help address this gap in current transfusion learning provision. That said, it is important to emphasise that mistakes occur within complex healthcare systems and require multiple approaches. Further research is therefore required to promote the SBC app in medical education, and to assess its potential impacts on clinical practice and patient outcomes.

### 10.4.2 Implications for medical app design

There are many factors that lead to weaknesses in medical apps. Preventing them require a change in mindset and development practices. Many medical app projects appear to adopt a shortsighted approach, which can be summed up as: “We need an app for that. Let’s hire someone to build it for us and promote it.”. One problem with this approach is that it commits little or no resources to evaluate the impact of the intervention. Similarly, the technical work is “outsourced” and the app’s code becomes a “black box” controlled by an external party. This makes it difficult and expensive to inspect the quality of the code, and to maintain it after launch.

In contrast, producing and supporting high quality medical apps require a strategic approach that recognises the critical role of iterative design, evaluation and maintenance. This requires longer-term funding, higher levels of clinician involvement and close interdisciplinary collaborations with software developers, designers and health-care evaluators. It may also involve training and capacity-building to ensure members of staff have the required skills to evaluate, implement and maintain information technology interventions.

For this reason, I propose that future work should consider the CREDIBLE principles presented in table 10.1. The principles are geared towards anyone about to embark on a medical app development project and who would benefit from consulting a brief list of key considerations.

Table 10.1: CREDIBLE principles for better medical apps.

	Principle	Rationale	Strategies
C	<b>Collaborate</b> with stakeholders.	To gain support and buy-in from users, subject experts and gatekeepers.	Identify and approach a small number of key people to work with. Negotiate organisational and political demands pragmatically. Adopt methods and tools to support collaborative activities. Be open-minded and ready to compromise to resolve disagreements.
R	<b>Research</b> the issue and similar work.	To refine goals, context and methods, and learn from what's gone before.	Search broadly for related work and contact people who have tackled similar issues in the past (perhaps it is possible to extend their work). Identify and evaluate existing tools and design methods. Revise aims, assumptions, methods, audience and scope accordingly.
E	<b>Evidence</b> in-app recommendations and content.	To demonstrate that the app is based on best available evidence.	Incorporate citations to current peer-reviewed literature. When scientific consensus is lacking, represent the range of current opinion or signal and justify specific stance adopted. Be prepared to publish updates as new evidence becomes available.
D	<b>Document</b> core assumptions.	To help users understand the origin, purpose and scope of the app.	Prominently highlight the purpose, scope, target audience, intended use and any significant limitations of the app. Offer details of authors and contributors, including contact details.
I	<b>Iterate</b> the design with users.	To improve usability and reduce risk of errors due to poor design.	Schedule user testing sessions early in the development process so that improvements can be incorporated in a timely fashion. Adopt user-centered design and agile software development methods.
B	<b>Budget</b> for the full app life-cycle.	To ensure resources are available over the whole life of the app.	The cost of an app is greater than any single 'upfront' design cost. Budget for an iterative design process, evaluation, training, promotion and future maintenance (typically over several years).
L	<b>Learn</b> as you go and share lessons.	To continuously improve, improve team skills and advance knowledge.	Highlight the "learning journey/curve" and the need to be flexible. Reflect on the process and modify as needed to achieve the goals. Identify and disseminate lessons learned. Invest in training and up-skilling of in-house staff.
E	<b>Evaluate</b> the app on key outcomes.	To test the design and generate strong evidence to encourage adoption.	Incorporate formative evaluation into the iterative design process. Conduct the most rigorous evaluation of the app using the strongest available outcome measures given the constraints of the project. Publish the results of the evaluation.

While these principles were designed to apply widely, they cannot be exhaustive. There is great diversity of medical app projects which cannot be catered to in a single table. For example, projects seeking to produce apps that potentially fall under the medical device regulation should take legal advice. Similarly, while these principles may be helpful, they were not written for commissioners of medical apps in mind.

# **Part IV**

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**Part V**

**APPENDICES**





# Appendix A:

## Interviews with practitioners

### A.1 Information and consent form

AN APP FOR CHECKING INDICATORS FOR IRRADIATED AND CMV NEGATIVE BLOOD

Karl Monsen. PhD candidate at the University of Edinburgh, UK.

[[personal contact details removed]]

Dr. Brian McClelland. SNBTS (retired). Medical adviser to project, Edinburgh, UK.

[[personal contact details removed]]

#### 1. Introduction

Errors continue to occur in the ordering of special blood components. In 2011, 69 cases were reported in the UK where irradiated and Cytomegalovirus (CMV) negative components were indicated but not requested. We have developed an app to aid prescription of irradiated and CMV negative blood. Additionally there are apps aiming to reduce unnecessary transfusion, such as the Mayo Clinic TransFuse iPad app and the NHSBT Platelets webapp, which we are interested in evaluating.

There is some controversy over the use of apps in medicine and a dearth of published evidence to demonstrate their effectiveness. We need your help to facilitate access to clinical staff involved in transfusion decision making to evaluate the apps.

#### 2. What we need from you

*Names and email addresses of staff involved in transfusion decisions.* We propose to evaluate the usability of the apps by means of an online survey and a follow up focus group.

*Advice on how to evaluate the quality of transfusion decisions.* We are interested in understanding whether and how apps can help improve the speed and accuracy of decision making in transfusion. This includes understanding causes of errors and how to evaluate decisions where evidence is lacking.

*Advice on whether clinical apps flag up legal-ethical issues.* “In the United Kingdom apps that are ‘medical devices’ must be registered with the MHRA [...] what constitutes a medical device is a grey area—for example, the agency said that an app that charted changes in skin moles would not be a device, whereas one that offered diagnosis would be” (McCartney, 2013, 1), <http://www.bmj.com/content/346/bmj.f1811>

*Comments and feedback on the apps* Any data you provide will be treated confidentially. Your answers will be made anonymous in any publications. You may withdraw your data at any time and for any reason. Please ask if you have any questions about any of the above.

Please sign below to indicate your informed consent:

.....

Participant Name

.....

Signature and date

.....

## A.2 Topic guide

### INTRODUCTION

- Who we are, our affiliations.
- Why we are working together.
- What the research project is about.
- Why we have arranged the meetings.
- Hand out informed consent form for participants to read through and sign.
- Check for any questions at this point.
- Ask if happy that we record the meetings.

If yes, turn on audio recorder.

### MAIN MATTER

#### 1. Special requirements app.

Explain that this is the app we have developed, intended for clinical decision making and education by answering the question 'Does my patient require irradiated or CMV negative components?' We showed all participants this app.

#### 2. NHSBT platelets app

Explain that this app was not developed by us and was designed to help prescribe platelets conservatively. We showed all participants this app as a point of comparison to our app.

#### 3. Mayo Clinic TransFuse app

When time allowed, and we felt it was relevant to the participants specialisms (e.g. anaesthetists), we showed this free game-based learning app to promote conservative use of blood.

#### 4. Australian Blood Service website on indications for irradiated blood

We discovered this website during the last day of meetings. Because it was quite similar to our app, we decided to show it to one participants, as a point of comparison to the app we are developing.

### TOPIC GUIDE FOR EACH APP/WEBSITE

- General impression and perceived usefulness?
- Scope and correctness of content?
- Audience, how to reach them and evaluate impact of app?
- Usability?

NB: Where it was possible, we conducted simple usability testing by asking participants to think aloud whilst finding their way around the app or website without our help. We used two iPads, an iPhone and NHS computers running Windows XP and Internet Explorer.

#### CONCLUDING

- Ask any outstanding questions, including returning to questions on consent sheet.
- Remind participants to sign and return consent sheet.
- Ask if participants are happy that we contact them again.

### A.3 Follow-up message

Dear <name>

I hope you are well. It was a pleasure to meet you at the end of April to talk about the app with indications for irradiated and CMV negative blood that Brian McClelland and I are developing.

We have been quietly working away for the last six months:

- Aligning the app's recommendations to BCSH and SaBTO guidelines.
- Adding a section with background information, common mistakes and good practice.
- Creating a simple 'algorithm', which points users to the relevant indications.
- Improving the usability

We would now like to invite you to have a look at the new version, which is available online at: <http://www.optimalblooduse.eu/app/>

There is a facility for leaving feedback in the app/webpage (scroll to the very end and press the green 'leave feedback' button). This will take you to an online form where you can evaluate the app and leave feedback.

Alternatively, simply reply to this email with your comments. If you include a phone number, a date and a time, I can call you to go through your feedback.

I am presenting the app on the 18th of October at the BBTS annual conference. Hence it would be very useful if you could find some time to look at the app in the next week or so (thus hopefully eliminating any glaring omissions or errors!).

There is a section in the app for acknowledgements. If you would like to be named there, please provide me with your:

Title, name, position and affiliation (as you want it to appear)

We would also acknowledge you in the BBTS presentation.

Thank you once again for your help. Brian and I look forward to hearing your thoughts.

Kind regards,

Karl Monsen

PhD student at The University of Edinburgh

# Appendix B:

## Web App Editor evaluation

### B.1 Survey consent and questions

#### Mobile apps development

##### 1. Introduction

Many people own a smartphone, but very few people know how to make apps. I would like to know if you think the approach we used in the course could encourage more people to develop apps.

##### 2. Research team and contact details

Karl Monsen. PhD candidate at the University of Edinburgh, UK.

[k.monsen@ed.ac.uk](#)  
0131 5527 1846

##### 3. Terms of participation

- Any data you provide will be treated confidentially.
- Your answers will be made anonymous in any publications.
- You may withdraw from this research at any time and for any reason.
- Please contact me if you have any questions about any of the above.

Proceeding indicates your informed consent to participate in the research.

There are five pages to this survey, which should take no more than 10 minutes to complete.

Thanks

Thinking about your experience of using mobile phones, please rate the following:

	Never	Rarely	Sometimes	Frequently	Always
I use a mobile phone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I use apps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I install apps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I rate apps.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I write reviews of apps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I create apps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments (use to elaborate your answers)

Please rate the following statements about mobile app development:

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
Mobile apps would be better if more users were able to contribute to them.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Users are more likely to contribute to apps if it was simple to do so.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Developing my own mobile app using the online code editor was easy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am likely to work on mobile apps in the future.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Comments (use to elaborate your answers)					
<div></div>					

Thinking about the online code editor, please rate the following statements:

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
Changing the code to include my own content was easy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changing the structure of the app, for example by adding or renaming pages, was easy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changing the core functionality or main purpose of the app was easy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I learnt a lot by looking at the code examples.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Thinking about the online code editor, please rate the following statements: \*

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I thought there was too much inconsistency in this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would imagine that most people would learn to use this system very quickly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system very cumbersome to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt very confident using the system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I needed to learn a lot of things before I could get going with this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would like to use this system frequently.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system unnecessarily complex.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought the system was easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would need the support of a technical person to be able to use this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the various functions in this system were well integrated.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Comments (use to elaborate your answers)					
<div></div>					

Thinking about your technical skills, please rate the following statement:

	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
I have a good grasp of HTML.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have a good grasp of Javascript.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have a good grasp of Cascading Style Sheets.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall I feel confident about my technical skills.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments (use to elaborate your answers)

Do you think the approach we used in the course could encourage more people to develop apps? Please explain your reasoning.

Please enter your name (only used to identify whose app I can use -- your answers will still be reported anonymously)

I give my permission to have screenshots of the app I developed during the course to appear in an academic paper and presentation. \*

- ☐ yes  
☐ no

Please select your age group

- ☐ 24 and under  
☐ 25-34  
☐ 35-44  
☐ 45-54  
☐ 55-64  
☐ 65 and over



## B.2 Interview consent and topic guide

### **Evaluation of an online editor for collaborating on mobile web apps: Information Sheet For Participants (v. 1, updated 23 July 2014)**

I would like to invite you to participate in a research interview. Before you decide whether to take part, I want you to know why I need your help and what's involved in taking part.

#### **1. What is the aim of the research?**

The purpose of the interview is to help understand how you used the web app editor, what benefits and problems you encountered, and how one could improve its design.

#### **2. What will you be asked to do?**

Answer questions from the below indicative list of topics:

1. Are you happy for me to record the interview?
2. Your background and why you became interested in software development?
3. The background and aim of the project? Why did you decide to work on it?
4. How did you determine which technologies to use? What were the pros and cons of HTML5?
5. How you were introduced to and why you agreed to test the web editor?
6. How did you use the editor for? What tasks did it do well? What tasks did it do poorly on?
7. What other IDEs have you used? (JSfiddle, JSbin, Eclipse, Netbeans, Visual Studio) and how does the system compare?
8. Did you at any point invite any other users to use the editor? If so, in what ways did the editor allow you to collaborate with others?
9. How did you feel about using using version control using Git?
10. Did the editor make it easier to do version control compared to command line or a GUI-based git client?
11. On the whole, are you satisfied with the outcome of your project so far, why or why not? Is there anything you would you have done differently?
12. What will happen next in your project? Will someone continue to improve and maintain the app?

13. Will you keep it hosted on GitHub and encourage others to contribute to your app?
14. If so, have you thought about using a particular software license?
15. Are you agreeable to reporting your answers using your real name or do you require anonymity?
16. Do you grant me permission to allow me to use screenshots of your app in my thesis?

**3. How will we maintain your privacy and confidentiality?**

Any data that you provide will be treated confidentially. Your answers can be reported anonymously if so desired in publications. The data will be held securely for the duration of the research (3 years) and then destroyed.

**4. Who is Conducting the Research?**

The research is led by Mr Karl Monsen (contact details omitted)

**5. Do you agree to participate?**

Participation in the research is voluntary. Any data you provide will be treated confidentially. Your answers will be made anonymous in any publications. You may withdraw your data at any time and for any reason. Please ask if you have any questions about any of the above. Sign below to indicate your informed consent to participate:

.....

This page is intentionally left blank.

# Appendix C:

## Survey of medical students

### C.1 Participant information sheet

Before participants could leave feedback, they were provided with the following information.

Thank you for exploring the Special Blood Request application, which aims to make it quick and easy to learn about, look up and test your knowledge of the indications for irradiated and cytomegalovirus (CMV) negative blood components.

#### 1. Research objectives

Special Blood Request is an early prototype and not a finished product. We now want to gain more structured feedback from potential users to help evaluate and shape the design.

#### 2. Terms of participation

Any data you provide will be treated confidentially. Your answers will be made anonymous in any publications. You may withdraw from the research at any time and for any reason. Please contact us if you have any questions about any of the above.

#### 3. Research team and contact details

Karl Monsen. PhD candidate at The University of Edinburgh, UK.

[[Contact details removed]]

Dr. Brian McClelland. SNBTS (retired). Medical adviser to project, Edinburgh, UK.

[[Contact details removed]]

#### 4. The questions

There are 16 questions split over eight pages. They should take about 5 minutes to complete. Press "next page" to begin. By proceeding you give your informed consent to participate in the research.

### C.2 Terms of use

The following information was offered to users of the app when they first accessed it:

#### Terms of use

Use of the app is subject to these terms. Please read them.

### **Disclaimer**

Special Blood Request (“the app”) was created during a PhD research project and is made available for evaluation use only. There may be inaccuracies in the content. The developers and contributors cannot be held liable for any harm resulting from the use of the app. The app is not intended to be a substitute for local hospital guidelines, professional medical advice, diagnosis, or treatment. Always seek the advice of a qualified health provider with any questions regarding medical matters.

The app is based on (but in no way endorsed by) the British Committee for Standards in Haematology (BCSH) 2010 guidelines on the irradiation of blood components and the 2012 position statement on the use of CMV negative blood components by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

Recommendations for irradiated and CMV negative blood components is only displayed in the app when it is indicated or contraindicated in these national UK guidelines. Guidance may not be appropriate in all patient situations. Local hospital policies may differ.

### **Data protection - what data we collect and how we use it**

The app is developed for a research project seeking to evaluate and improve the design of clinical apps. The use of the app is therefore monitored. We may publish our findings in scholarly publications, observing the usual academic principles of anonymity, informed consent and voluntary participation. The following data is recorded:

- Which pages you visit and for how long.
- Information about your computing device (operating system, screen resolution, browser, IP address).
- Your approximate geographical location (country, city).
- Your responses to the quiz.
- Keywords that you input in the app’s search functionality.

If you choose to provide additional feedback (using the ‘leave feedback’ button), we may correlate your browsing behaviour with your feedback answers to help us better understand the strengths and weaknesses of the app design. To do this we store a browser cookie on your device.

We do not collect any personally identifying information, unless you disclose this through the online feedback form.

**No warranty**

THE SOFTWARE IS PROVIDED "AS IS", WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. IN NO EVENT SHALL THE AUTHORS OR COPYRIGHT HOLDERS BE LIABLE FOR ANY CLAIM, DAMAGES OR OTHER LIABILITY, WHETHER IN AN ACTION OF CONTRACT, TORT OR OTHERWISE, ARISING FROM, OUT OF OR IN CONNECTION WITH THE SOFTWARE OR THE USE OR OTHER DEALINGS IN THE SOFTWARE.

## C.3 Evaluation questionnaire

Page 1 of 8

## 1. Overall reaction

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
I can definitely see an use for this app.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My experience of using the app was enjoyable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am likely to use this app again.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would recommend this app to others.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate whether you agree or disagree with the statements.

Please elaborate your ratings

Use this space to explain your ratings. If you gave a low rating please explain why? And vice versa. Could you say something about the apps's strengths and weaknesses?

&lt; Previous Page

Next Page &gt;

Page 2 of 8

2. Did anything not work properly?

Please describe any behaviour of the system that was unexpected or incorrect. Please provide a clear description of what was wrong (e.g. which part of the system) and why you thought it was wrong (e.g. what you expected to happen).

3. Did you find any erroneous, dubious, incorrect or unclear information?

Please provide enough detail so we can locate the erroneous text and amend it.

&lt; Previous Page

Next Page &gt;

Page 3 of 8

4. How would you describe the "information" section of the app?

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
It covers all the most important points.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is succinct and easy to read.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is appropriately referenced.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is worth reading.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate whether you agree or disagree with the statements. The information section discusses the rationale for providing irradiated and cmv negative components to at risk patients, common mistakes and how to prevent them.

Comments (use to elaborate your answers)

Use this box to elaborate your answers. For instance, was anything missing or irrelevant? Should the section be expanded or shortened? What do you think users might benefit the most from reading? Was anything unclear or incorrect?

&lt; Previous Page

Next Page &gt;

Page 4 of 8

5. How would you describe the "indications" section of the app?

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
Looking up the indications is quick and easy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Recommendations are clear and unambiguous.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The app reflects the clinical guidelines correctly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The indications are appropriately referenced.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate whether you agree or disagree with the statements.

Comments (use to elaborate your answers)

Use this box to elaborate your answers. For instance, did you find what you were looking for? Were the indications presented appropriately? Was anything unclear?

&lt; Previous Page

Next Page &gt;



Page 5 of 8

6. How would you describe the "checklist" section of the app?

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
Exhaustive and comprehensive.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Logically structured.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Quick and easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fail safe.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments (use to elaborate your answers)

Use this box to elaborate your answers. For instance, do you think the checklist is a good way of presenting the list of indications? Why or why not? Could the algorithm be improved? Can you think of any cases which are not covered?

&lt; Previous Page

Next Page &gt;

Page 6 of 8

7. How would you describe the "quiz" section of the app?

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
The quiz questions are well-phrased.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The answer feedback is clear.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is likely to help memorise the indications.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The quiz is an useful way of learning.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments (use to elaborate your answers)

Use this box to elaborate your answers. For example, are there questions which you think should be added to the quiz? Are there current questions which are hard to answer? Do you have any suggestions for how the quiz might be improved to encourage deeper learning or make it more engaging?

&lt; Previous Page

Next Page &gt;

Page 7 of 8

The following questions are part of a standard usability inventory. Please answer them as best you can.

## 8. Usability inventory

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I thought there was too much inconsistency in this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would imagine that most people would learn to use this system very quickly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system very cumbersome to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt very confident using the system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I needed to learn a lot of things before I could get going with this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would like to use this system frequently.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system unnecessarily complex.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought the system was easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would need the support of a technical person to be able to use this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the various functions in this system were well integrated.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. Which of the following descriptions best fit your current job role?

- None -

If other, please specify

10. What is your main department?

- None -

11. How frequently do you carry out the following tasks?

	Every day	Once a week	Once a month	Once a year	Never
Prescribe blood transfusions for patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Order blood transfusions for patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Verify requests for blood transfusions.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Administer blood transfusions to patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advice patients about blood transfusion issues.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Discuss indications for blood transfusions with staff or colleagues.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Work with patients who have special requirements*.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

\* Special requirements refers to irradiated and CMV negative blood components.

12. Please rate the following statements about special requirements\*

	Strongly disagree	Disagree	No opinion	Agree	Strongly agree
I often prescribe, process or administer special components.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel confident about the indications for special components.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Guidance for prescribing special components is easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having access to an app for special components would be useful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

\*Special requirements refers irradiated and CMV negative blood components.

13. Do you use a smartphone?

14. What device are you currently using?

Please select the description that best matches the device you used when you tried the app.

Device model

If you know the model name of your device, please enter it here.

15. Please indicate your age group

16. Any final comments?

If you would like to be acknowledged as a contributor in the app, please state your title, name, position and affiliation.

The app has a section for acknowledgements. If you enter your details, we will add it to the list of acknowledgements.

Press the "Submit" button to send us your answers. Thank you!

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# Appendix D: Web App Trial evaluation

## D.1 First invitation to practitioners

Sent: 2014-11-10 08:54:01 to all 336 selected practitioners (5 messages bounced)

Subject: SPECIAL Blood Components Study invitation

From: Special Study specialstudy@optimalblooduse.eu

Message:

Dear [FIRSTNAME] [LASTNAME]

We would like your support to evaluate a new educational app in transfusion medicine aiming to improve staff knowledge of special requirements and patient safety. Failures to provide patients with irradiated and cytomegalovirus (CMV) negative blood components are frequently reported to Serious Hazards of Transfusion (SHOT), putting patients at unnecessary risks.

You have been invited to participate in the study because you have recently completed Module 1 Safe Transfusion Practice. Taking part will require approximately 15 minutes. For more information and to participate please follow the link below: [http://optimalblooduse.eu/specialstudy/?i=\[EVALUATIONCODE\]](http://optimalblooduse.eu/specialstudy/?i=[EVALUATIONCODE])

The completion date for the evaluation is November 24, 2014.

Your participation is really valuable and will contribute to providing new evidence about app based learning. All participants in the study will have the choice of entering into a draw for a chance to win a £50 national book voucher.

The study is endorsed by the Chair of [[healthboard removed]] Transfusion Committee and has approval from [[healthboard removed]] Clinical Governance & Risk Management Support Team. The project is conducted by researchers at The University of Edinburgh in collaboration with the Better Blood Transfusion Team at the Scottish National Blood Transfusion Service.

Thank you for taking the time to read this email and considering participating in the study.

Yours Sincerely,

[[Chair of the Transfusion Committee removed]]

Mrs. Susan Cottrell, Nurse Specialist in Education, Better Blood Transfusion, SNBTS.

Mr. Karl Monsen, PhD candidate at the University of Edinburgh.

## D.2 Reminder to practitioners

Sent: 2014-11-24 15:14:38 to all 336 participants (6 messages bounced)

Subject: Evaluation of a new app in transfusion medicine

From: SPECIAL Study specialstudy@optimalblooduse.eu

Message:

Dear [FIRSTNAME] [LASTNAME]

Two weeks ago we asked you to help us evaluate a new educational app in transfusion medicine, but we have not heard back from you. With your help we will know if the app improves staff knowledge and is likely to reduce mistakes in the care of patients who require irradiated and/or CMV-negative blood transfusion. We understand that this is a very busy time of the year, so we have extended the deadline for completing the online evaluation until December 8, 2014. Participating is easy and should take less than 15 minutes, simply follow the link below: [http://optimalblooduse.eu/specialstudy/?i=\[EVALUATIONCODE\]](http://optimalblooduse.eu/specialstudy/?i=[EVALUATIONCODE])

We hope that you will support our effort to reduce the risks associated with blood transfusions and decide to take part in the study. All participants will have the choice of entering into a draw for a chance to win either a £50 national book token voucher or an Apple Ipod Shuffle audio player, which can be engraved with a message of your choice.

Thank you for considering to take part in the study.

Yours Sincerely,

[[Chair of the Transfusion Committee removed]]

Mrs. Susan Cottrell, Nurse Specialist in Education, Better Blood Transfusion, SNBTS.

Mr. Karl Monsen, PhD candidate at the University of Edinburgh.

The study is endorsed by the Chair of [[healthboard removed]] Transfusion Committee and has approval from [[healthboard removed]] Clinical Governance & Risk Management Support Team. The project is conducted by researchers at The University of Edinburgh in collaboration with the Better Blood Transfusion Team at the Scottish National Blood Transfusion Service.

## D.3 Second reminder to practitioners

Sent: 2014-12-08 03:42:33 to 160 non-respondents in arm 2 (app group) (3 bounced).

Subject: Help us appraise an app for special requirements in transfusion

From: SPECIAL Study specialstudy@optimalblooduse.eu

Message:

Dear [FIRSTNAME] [LASTNAME]

We recently requested your help to evaluate a new educational app about the use of special blood components. This is an area of blood transfusion where mistakes are frequently reported, putting patients at unnecessary risks.

For anyone who have not yet had a chance to take part in the study, we have extended the deadline by another week. Should you wish to participate, please complete the online evaluation before Monday December 15 2014 by following the link below:

[http://optimalblooduse.eu/specialstudy/?i=\[EVALUATIONCODE\]](http://optimalblooduse.eu/specialstudy/?i=[EVALUATIONCODE])

Participating is easy and should take less than 15 minutes. All participants have the choice of entering into a draw for a chance to win either a £50 national book token voucher or an Apple Ipod Shuffle audio player. We hope that you will support our effort to reduce the risks associated with blood transfusions and decide to take part in the study. We will not extend the deadline again or send any further invitations.

Thank you for considering to take part in the study.

Yours Sincerely,

[[Chair of the Transfusion Committee removed]]

Mrs. Susan Cottrell, Nurse Specialist in Education, Better Blood Transfusion, SNBTS.

Mr. Karl Monsen, PhD candidate at the University of Edinburgh.

The study is endorsed by the Chair of [[healthboard removed]] Transfusion Committee and has approval from [[healthboard removed]] Clinical Governance & Risk Management Support Team. The project is conducted by researchers at The University of Edinburgh in collaboration with the Better Blood Transfusion Team at the Scottish National Blood Transfusion Service.



## D.4 Participant information sheet

After opening the link in the email, participants were presented with the following information about the study, and asked to indicate their informed consent:

[[University of Edinburgh Logo]]

Stopping and Preventing Errors in CMV-negative and Irradiated blood transfusion through App-based Learning (SPECIAL).

We would like to invite you to participate in the SPECIAL study. Before you decide whether to take part, click on the headings below to find out why we need your help and what we will ask you to do.

### 1. What is the aim of the research?

Blood transfusion is a complex process and about one hundred mistakes related to the provision of irradiated and Cytomegalovirus (CMV) negative blood ("special blood components") are reported every year to Serious Hazards of Transfusion (SHOT) in the UK.

Researchers at the University of Edinburgh are collaborating with experts in transfusion to create an app with learning materials about special blood components for staff involved in key stages of the transfusion process. This pilot study will evaluate whether the app increases knowledge of the correct use of special blood components.

### 2. What will I be asked to do?

We are asking you to answer two sets of 8 multiple choice questions about special blood components. After the first set of questions, you will be presented with [[medical guidelines (displayed if participant randomised to arm 1)]] [[the Special Blood Components app (shown if participant randomised to arm 2)]] to help you answer the remaining questions.

Taking part in the study should take you about 15 minutes. You can choose to participate at a time and from a location that is convenient to you. You will need access to a computer or mobile device with an Internet connection.

### 3. Why should I participate?

By taking part, you will help shape the design of a new learning resource. If results are positive, wider dissemination of the app could reduce mistakes and enhance patient safety. Taking part in the study is also an excellent opportunity to test your knowledge in a safe environment, although we regret we are unable to provide you with a test score.

Additionally, there is a chance to win a £50 national book token voucher or an engraved Apple iPod Shuffle audio player. Participation is completely voluntary and there are no risks to

participating.

4. How will you use my data?

Any data that you provide will be treated confidentially and your answers will be reported anonymously in publications. The information will be held securely for the duration of the research project (3 years) and then destroyed.

5. Who are you asking to participate?

We are inviting all grades of doctors, registered nurses, midwives and transfusion laboratory staff who recently completed the Module 1 Safe Transfusion Practice (or equivalent) using the Learn Better Blood Transfusion programme from three NHS [[name of healthboard removed]] hospitals.

[[List of hospitals removed]]

Staff who do not meet these criteria are excluded from participating. If you have received a personal email invitation from the research team you are likely to be eligible.

6. Who is conducting the research?

The research is conducted by Mr. Karl Monsen, a PhD candidate at The University of Edinburgh, in collaboration with Mrs. Susan Cottrell, Nurse Specialist in Education, at The Better Blood Transfusion Team, The Scottish National Blood Transfusion Service.

The study is endorsed by [[chair of the healthboard Transfusion Committee removed]], and Dr. Brian McClelland is medical adviser to the project.

If you have any questions, please contact Karl at the following email address:

[[Email address removed]]

Alternatively, you can write to:

[[Mail address removed]]

Thank you for your time.

The study has approval from [[healthboard removed]] Clinical Governance and Risk Management Support Team.

Ready to begin?

Press the green button to indicate that you have read the above information and freely consent to take part in the study. [[Green button labelled "I agree to participate"]]

## D.5 Items in the knowledge test

The knowledge test was composed of 16 questions, divided into two groups. The first group of questions (items 1 to 8) probed participants knowledge of special blood components. This included, how special blood components are prepared, how they should be administered, how they prevent transfusion complications and reasons for why mistakes can happen.

The second group of question (items 9 to 16) probed participants knowledge of the indications for special blood components, by asking them to select the correct blood component in eight patient scenarios. The questions are given below, together with their answer options, the correct answer (in bold), the item difficulty (percentage of participants who answered it correctly) and item discrimination, calculated from the point-biserial correlation with data from all 61 study respondents (Varma, no year).

### 1. Which of the following are cellular blood components?

- Red cells
- Platelets
- White cells
- **All of the above**
- None of the above
- Don't know

Item difficulty: easy (85.2%).

Item discrimination: good (biserial correlation: 0.298).

### 2. What are risk factors for Transfusion Associated Graft versus Host Disease?

- Shared HLA haplotype between donor and recipient
- Viable donor lymphocytes in component
- Severe T-lymphocyte immunodeficiency in recipient
- **All of the above**
- None of the above
- Don't know

Item difficulty: hard (31%).

Item discrimination: acceptable (biserial correlation: 0.174).

**3. How is the risk of Transfusion Associated Graft versus Host Disease best prevented?**

- Leucodepletion
- Methylene blue treatment
- **X-ray or gamma irradiation**
- All of the above
- None of the above
- Don't know

Item difficulty: hard (36%).

Item discrimination: good (biserial correlation: 0.353).

**4. How can the risk of cytomegalovirus (CMV) infection be minimised?**

- Restrictive use of transfusion
- Use of CMV-negative blood
- Leucocyte depletion
- **All of the above**
- None of the above
- Don't know

Item difficulty: medium (59%).

Item discrimination: acceptable (biserial correlation: 0.232).

**5. What statements about leucodepletion (LD) in the UK are correct?**

- LD significantly reduce white cells
- All red cells and platelets are LD

- Granulocytes cannot be LD
- **All of the above**
- None of the above
- Don't know

Item difficulty: hard (30%).

Item discrimination: good (biserial correlation: 0.468).

**6. What statements about irradiation of blood components in the UK are true?**

- All red cells are routinely irradiated
- **Irradiation inactivates lymphocytes**
- Irradiation increases component shelf life
- All of the above
- None of the above
- Don't know

Item difficulty: medium (45%).

Item discrimination: good (biserial correlation: 0.339).

**7. For how long should patients with Hodgkin's lymphoma receive irradiated blood?**

- **Indefinitely**
- Six months
- Three months
- Case by case decision
- Irradiation is not required
- Don't know

Item difficulty: medium (54%).

Item discrimination: good (biserial correlation: 0.433).

**8. Why do patients fail to receive irradiated blood appropriately?**

- Poor handover in shared care
- Mistaken patient identity
- Errors in information systems
- **All of the above**
- None of the above
- Don't know

Item difficulty: easy (82%).

Item discrimination: good (biserial correlation: 0.309).

**9. Red cells donated by a mother to her two year old child.**

- Irradiated & CMV negative
- **Irradiated**
- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: hard (26%).

Item discrimination: good (biserial correlation: 0.236).

**10. Red cells for an adult male treated with Alemtuzmab (Campath).**

- Irradiated & CMV negative
- **Irradiated**

- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: medium (50%).

Item discrimination: good (biserial correlation: 0.308).

**11. Elective red cell transfusion for an immunocompetent pregnant woman in second trimester.**

- Irradiated & CMV negative
- Irradiated
- **CMV negative**
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: medium (46%).

Item discrimination: good (biserial correlation: 0.313).

**12. Fresh frozen plasma for a patient with Hodgkin's lymphoma.**

- Irradiated & CMV negative
- Irradiated
- CMV negative
- **No special component required**
- Not enough information to answer
- Don't know

Item difficulty: hard (25%).

Item discrimination: good (biserial correlation: 0.338).

**13. HLA-matched platelets for an elderly female patient with refractoriness.**

- Irradiated & CMV negative
- **Irradiated**
- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: medium (39%).

Item discrimination: good (biserial correlation: 0.422).

**14. Platelets transfused in utero to treat neonatal alloimmune thrombocytopenia.**

- **Irradiated & CMV negative**
- Irradiated
- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: medium (53%).

Item discrimination: good (biserial correlation: 0.348).

**15. Red cells for an eight year old girl who had a bone marrow transplant within the last 3 months.**

- Irradiated & CMV negative



- **Irradiated**
- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: hard (25%).

Item discrimination: good (biserial correlation: 0.264).

**16. Platelets for a 60 year old male receiving purine analogue drugs.**

- Irradiated & CMV negative
- **Irradiated**
- CMV negative
- No special component required
- Not enough information to answer
- Don't know

Item difficulty: medium (53%).

Item discrimination: good (biserial correlation: 0.538).

## D.6 Flow through the Web App Trial



THE UNIVERSITY of EDINBURGH

### **Stopping and Preventing Errors in CMV-negative and Irradiated blood transfusions through App-based Learning (SPECIAL).**

We would like to invite you to participate in the SPECIAL study. Before you decide whether to take part, click on the headings below to find out why we need your help and what we will ask you to do.

#### **1. What is the aim of the research?**

Blood transfusion is a complex process and about one hundred mistakes related to the provision of irradiated and Cytomegalovirus (CMV) negative blood ("special blood components") are reported every year to Serious Hazards of Transfusion (SHOT) in the UK.

Researchers at the University of Edinburgh are collaborating with experts in transfusion to create an app with learning materials about special blood components for staff involved in key stages of the transfusion process. This pilot study will evaluate whether the app increases knowledge of the correct use of special blood components.

#### **2. What will I be asked to do?**

#### **3. Why should I participate?**

#### **4. How will you use my data?**

#### **5. Who are you asking to participate?**

#### **6. Who is conducting the research?**

### **Ready to begin?**

Press the green button to indicate that you have read the above information and freely consent to take part in the study.



**I agree to participate**

## Confirm eligibility

Please confirm that you are eligible to participate by answering the following questions:

### 1. At what hospital are you based?

### 2. What is your role?

Please enter your job title:

How many years of experience do you have?

What is your specialty?

### 3. Does your current place of work have patients who require CMV-negative or irradiated blood components?

Have you *previously* been part of a workplace with patients who require CMV-negative or irradiated blood components?

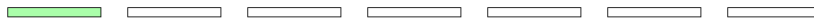
How long did you work there?

### 4. In your current role, how often do you work with patients who require CMV-negative or irradiated blood components?

### 5. How confident do you feel about the indications for irradiated and CMV-negative blood components?

## You are eligible to participate.

Press the green button to answer the first set of knowledge-based questions.

**Answer the questions by selecting an option from the list.**

Please answer without referring to outside help.

How can the risk of cytomegalovirus (CMV) infection be minimised?

**Use of CMV-negative blood**



Which of the following are cellular blood components?

**Red cells**



How is the risk of transfusion associated graft versus host disease best prevented?

**Methylene blue treatment**



What statements about irradiation of blood components in the UK are true?

**All red cells are routinely irradiated**



**Review your answers and press the green button to continue.**

**Next page**

**What special blood components are indicated in the following cases?**

Please answer without referring to outside help.

Elective red cell transfusion for an immunocompetent pregnant woman in second trimester.

**Irradiated & CMV negative**



Platelets transfused in utero to treat neonatal alloimmune thrombocytopenia.

**CMV negative**



Platelets for a 60 year old male receiving purine analogue drugs.

**No special component required**



Red cells for an adult male treated with Alemtuzmab (Campath).

**Not enough information to answer**



**Review your answers and press the green button to continue.**

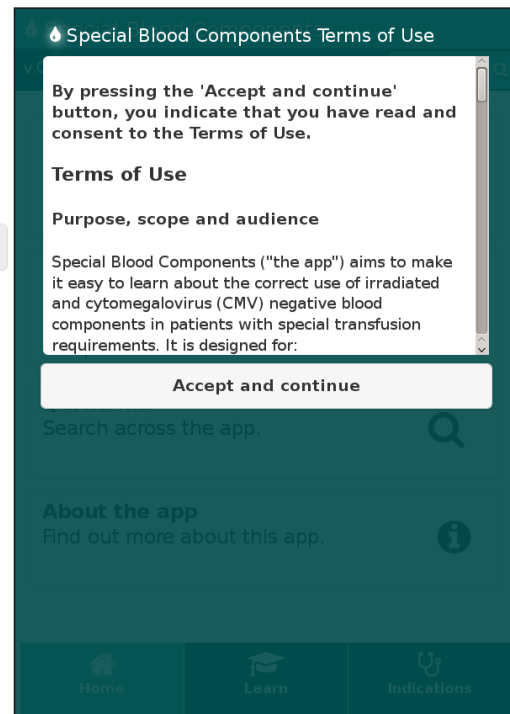
**Next page**



**You have completed the first set of questions.**

Please take a moment to study the Special Blood Components App (adjacent) before proceeding to answer the remaining questions.

☐ I am ready to proceed

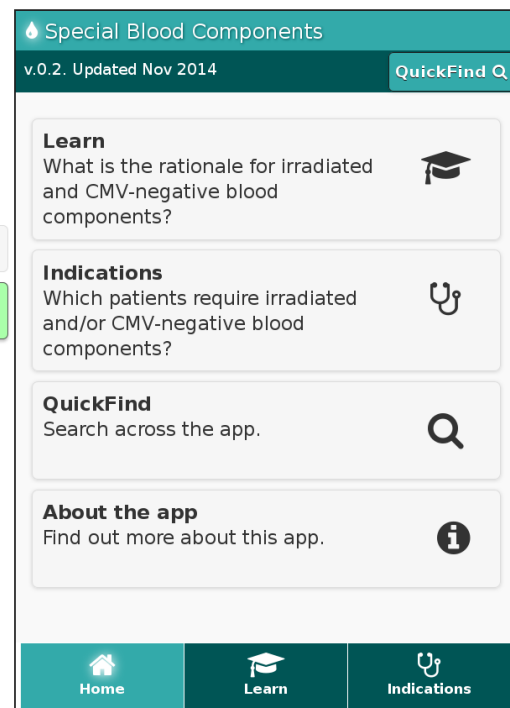


**You have completed the first set of questions.**

Please take a moment to study the Special Blood Components App (adjacent) before proceeding to answer the remaining questions.

☒ I am ready to proceed

**Proceed to remaining questions** >



Answer the questions by selecting an option from the list.

You may refer to the app (adjacent) when answering.

For how long should patients with Hodgkin's lymphoma receive irradiated blood?

Indefinitely

What are risk factors for transfusion associated graft versus host disease?

Shared HLA haplotype between donor and recipient

Why do patients fail to receive irradiated blood appropriately?

Mistaken patient identity

What statements about leucodepletion (LD) in the UK are correct?

All of the above

Review your answers and press the green button to continue.

Next page

Indications for irradiated and CMV negative blood components

< Back QuickFind Q

**Which patients require irradiated or CMV-negative blood components?**

Press an indication to show details.

Enter a search term. Results will show instantly. Clear ✕

hod

Indication

Hodgkin lymphoma.

**Irradiation is required.**

1. "All adults and children with Hodgkin lymphoma at any stage of the disease should have irradiated red cells and platelets for life (1B)." (bcsh2010)

Home Learn Indications

What special blood components are indicated in the following cases?

You may refer to the app (adjacent) when answering.

Fresh frozen plasma for a patient with Hodgkin's lymphoma.

**Irradiated**

HLA-matched platelets for an elderly female patient with refractoriness.

**Irradiated & CMV negative**

Red cells donated by a mother to her two year old child.

**CMV negative**

Red cells for an eight year old girl who had a bone marrow transplant within the last 3 months.

**Not enough information to answer**

Review your answers and press the green button to continue.

**Next page**

**Transfusion-Associated Graft versus Host Disease (TA-GvHD)**

< Back
Next >
QuickFind Q

### Transfusion-Associated Graft versus Host Disease (TA-GvHD)

TA-GvHD is a rare, almost universally fatal disease caused by the transfusion of cellular blood (red cells, platelets and granulocytes) components containing viable lymphocytes. The transfused donor lymphocytes engraft and attack the recipient, causing skin rash, diarrhoea, liver disease, bone marrow failure and death from infection often within two-three weeks of the transfusion ([HTM 2007, p.41](#)) ([BCSH 2010, p.41](#)), although the clinical picture may be longer in neonates.

#### Prevention and risk factors

TA-GvHD is prevented by exposing cellular blood components to a dose of 25-50 Gy of Gamma or X-ray irradiation, thus inactivating the donor lymphocytes that give rise to TA-GvHD ([BCSH 2010, p.41](#)). Only cellular blood components for patients at risk of TA-GvHD require irradiation. The risk of developing TA-GvHD depends on three factors ([BCSH 2010, p.37](#)):

Home

Learn

Indications

Please rate the following statements about the Special Blood Components App

It was easy to find what I was looking for.

Please select



It was enjoyable to use.

Please select



I would like to use it again.

Please select



I would recommend it to others.

Please select



Please explain your ratings

Did you find any confusing, erroneous, dubious, incorrect or unclear information? Did anything not work properly? Comment on any strengths and weaknesses.

Next page



Special Blood Components

v 0.2. Updated Nov 2014

QuickFind

**Learn**  
What is the rationale for irradiated and CMV-negative blood components?

**Indications**  
Which patients require irradiated and/or CMV-negative blood components?

**QuickFind**  
Search across the app.

**About the app**  
Find out more about this app.

Home

Learn


Indications




Have you used apps in your education or practice before?

Please select 


Is an app about special requirements going to be useful to you?

Please select 

Is there a need for more apps aiming to improve transfusion practice?

Please select 

If you use a smartphone or tablet device, where do you use it?

Please select 

Please indicate your age group

Please select 

Are you happy to be contacted by the researchers for follow up study in the future?

☐ Yes, I'm happy to be contacted (requires an email address)


Would you like to be entered into the draw for a £50 book voucher and an Apple iPod Shuffle?

☐ Yes, enter me in the draw (requires an email address)

Do you have any final comments you wish to share?

**You have completed all the questions.**

Press the green button to submit your answers.

Submit answers 

**You have completed the first set of questions.**

Please take a moment to study [healthboard removed] Special Requirements Guidelines (adjacent) before proceeding to answer the remaining questions.

☐ I am ready to proceed

**[healthboard removed] Special Requirements Guidelines**

Search document

Search guidelines Q

**Irradiated Components**

For at-risk patients, all red cell, platelet and granulocyte concentrates should be irradiated. It is not necessary to irradiate FFP, cryoprecipitate or fractionated plasma products.

- All intrauterine transfusions.
- All exchange or top-up transfusions in infants where there has been a previous intra-uterine transfusion, until 6 months after the expected delivery date.
- Exchange transfusion, with no previous intra-uterine transfusion; irradiated blood is recommended provided this does not unduly delay transfusion.
- Proven or suspected congenital immunodeficiency states (including Severe Combined Immunodeficiency (SCID), Di George's syndrome, Wiskott-Aldrich syndrome, purine nucleoside phosphorylase deficiency, reticular dysgenesis, cell-immunodeficiency (not otherwise specified), lymphocyte

**CMV Negative Components**

- Intra-uterine transfusion irrespective of the CMV status of the mother.
- Pregnant women antenatally (pre-delivery only). If CMV negative components are not readily available and a delay will compromise the mother or baby, CMV random components (i.e. untested) are an acceptable alternative.
- All blood transfusions for infants up to 28 days post expected delivery date.

Extract from [healthboard removed] Blood Transfusion Clinical Policy and Procedures 2013

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# Appendix G:

## Abbreviations and definitions

- **BBT (UK) - Better Blood Transfusion.**  
Initiative to improve UK transfusion safety, active between 1998 and 2012. Replaced by Patient Blood Management (JPAC, no year).
- **BBT (Scotland) - Better Blood Transfusion.**  
A multi-disciplinary team, formed in 2003 by the SNBTS to promote “safe, effective, efficient and appropriate transfusion for patients” (SNBTS, no year).
- **BCSH - British Committee for Standards in Haematology.**  
UK body responsible for national guidelines in haematology and transfusion medicine, including guidelines for irradiated blood components. A sub-committee of the BSH.
- **BSH - British Society for Haematology.**  
UK professional body for haematologists established in 1960. It is associated with the British Journal of Haematology and publishes guidelines developed by the BCSH.
- **CMV - Cytomegalovirus.**  
Herpes virus carried by about half the UK population. It causes asymptomatic infection in healthy individuals, but poses a risk to vulnerable patient groups. The virus remains latent in white blood cells and can be transmitted via blood transfusions (SaBTO, 2012b).
- **CSS - Cascading Style Sheets.**  
A web technology for controlling the layout and formatting of page elements in an HTML document, such as type face, colours and positioning.
- **EBM - Evidence-Based Medicine**  
“... de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research.” (Guyatt et al., 1992).
- **eHealth - Electronic healthcare**  
“eHealth is an emerging field of medical informatics, referring to the organisation and delivery of health services and information using the Internet and related technologies.” (Eysenbach, 2001).
- **Engraftment (of transfused blood cells)**  
Engraftment in the context of blood transfusion (and transplants more widely) occurs when blood cells (or transplanted organs) are introduced into a patient without being destroyed by their immune system, and instead becomes a functioning part of their body. It is a pre-condition for TA-GvHD.

- **FDA - Food and Drugs Administration.**  
US body responsible for regulating medicines, medical devices, food, cosmetics and other products, including medical apps that meet the definition of a medical device (FDA, 2015).
- **HLA - Human leucocyte antigen.**  
Proteins on the surface of cells, enabling the immune system to distinguish the body's own cells from foreign cells. The transfusion of HLA haplotype homozygous donor lymphocytes (i.e. donated blood cells that share cell surface proteins with the recipient) can lead to TA-GvHD (Treleaven et al., 2010).
- **HTML - Hypertext Markup Language.**  
A standard, currently in its fifth revision (HTML5), for creating web pages ("hypertext" documents) by enclosing portions of text using semantic tags ("marking up"). For example, a large heading can be created by wrapping text with the <h1> tag:  
<h1>This is a large heading</h1>
- **LBT - Learn Blood Transfusion.**  
E-learning program for blood transfusion developed by the BBT team at the SNBTS (SNBTS, no year).
- **mHealth - Mobile healthcare.**  
"Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices." (WHO, 2011, 6).
- **Medical App - Medical application.**  
Software application intended for patients or healthcare practitioners that is designed for use on a portable computing device, such as a smartphone. Medical apps are regulated under existing medical device legislation. According to the FDA (2015, 8), only those medical apps that are deemed to meet the criteria for a medical device (e.g. intended "for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease") and "whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended" are actively regulated.
- **MHRA - Medicine and Healthcare products Regulatory Agency.**  
UK body that regulates medicines and medical devices in the UK, including some medical apps (MHRA, 2014). Monitors the safety of blood transfusions through the SABRE scheme.
- **NICE - National Institute for Health and Care Excellence.**  
UK body that produces quality standards and evidence-based guidelines for health, public health and social care practitioners (NICE, no year).
- **NHSBT - National Health Service Blood and Transplant.**  
Body responsible for the safety and supply of blood, organs, stem cells and tissues,

formed in 2005 through a merger of the National Blood Service and UK Transplant ([NHSBT](#), no year).

- **RCOG - Royal College of Obstetricians and Gynaecologists.**  
Founded in 1929 to advance the science and practice obstetrics and gynaecology. Publishes the Green-Top Guidelines ([RCOG](#), no year).
- **SABRE - Serious Adverse Blood Reactions and Events**  
MHRA's system for monitoring incidents in UK blood transfusions.
- **SaBTO-Advisory Committee on the Safety of Blood, Tissues and Organs** Committee that "advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation" ([SaBTO](#), no year), including the use of Cytomegalovirus negative blood components ([SaBTO](#), 2012b).
- **SBC - Special Blood Components.**  
SBC is the name of the app that that was developed as part of the thesis. It refers to specially prepared blood components (CMV-negative and irradiated) that are indicated for patients at risk of TT-CMV and TA-GvHD.
- **SIGN - Scottish Intercollegiate Guidelines Network.**  
"... develops evidence based clinical practice guidelines for the National Health Service (NHS) in Scotland" ([SIGN](#), no year).
- **SNBTS - Scottish National Blood Transfusion Service.**  
"SNBTS is the specialist provider of transfusion medicine in Scotland, supplying high quality blood, tissues, cells and services" ([SNBTS](#), no year).
- **SHOT - Serious Hazards of Transfusion.**  
UK professionally-led haemovigilance scheme encouraging reporting, analysis and dissemination of lessons from incidents and near misses involving blood transfusions, established 1996 ([SHOT](#), no year).
- **TA-GvHD - Transfusion-associated Graft versus Host Disease.**  
A rare, almost universally fatal disease caused by the transfusion of cellular blood components (red cells, platelets and granulocytes) containing viable lymphocytes, that is prevented by irradiating cellular blood components prior to transfusion ([Treleaven et al.](#), 2010).
- **TT-CMV - Transfusion-transmitted CMV infection.**  
Cytomegalovirus infection (or re-infection) caused by transmission of the virus via blood transfusion. CMV infection is asymptomatic in a majority of adults worldwide, but can be fatal or cause lifelong disability in at-risk patients ([SaBTO](#), 2012b, 16).
- **WAE - Web App Editor.**  
A collaborative web-based editor that enables multiple authors to work together to build mobile apps. It is one of the outcomes of the thesis.

- **WAT - Web App Trial.**

A system for conducting pragmatic randomised controlled trials of medical apps. It was developed to evaluate the SBC app with healthcare practitioners.